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Guidance Package for Reregistration of Pesticide Products in Compliance with Naphthaleneacetic Acid Registration Standard

(U.S.) Environmental Protection Agency
Washington, DC

31 Jul 81

U.S. Department of Commerce
National Technical Information Service
NTIS

PB88-180492

GUIDANCE PACKAGE FOR REREGISTRATION OF PESTICIDE PRODUCTS IN COMPLIANCE WITH

Naphthaleneacetic Acid

REGISTRATION STANDARD

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION

WASHINGTON, DC

July 31, 1981

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15. Supplementary Notes This Registration Standard replaces (supercedes?) a previous standard that was mistakenly sent to NTIS in 1982. I have already asked Dottie Adams to pull PB82-131145 from your shelves. Again, this document supercedes PB82-131145.

16. Abstract (Limit: 200 words)

This document contains information regarding the registration of pesticide products containing the subject active ingredient. The document includes how to register under a registration standard, regulatory position and rationale, and summaries of data requirements and data gaps. Also included is a bibliography containing citations of all studies reviewed by EPA in arriving at the positions and conclusions contained in the standard.

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See Instructions on Reverse

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I. INTRODUCTION

This guidance package has been prepared to provide you, the registrant, with specific information with which you may maintain in effect your current registration(s) that is subject to this Registration Standard. (Refer to the cover letter's attachment for a listing of your affected products.) If for any reason you decide to request that the Agency discontinue the registration of any of your products subject to the registration requirement in this Standard, please notify the Product Manager named in the cover letter, within 90 days from the receipt of this package, that you wish to voluntarily cancel the registration(s). If you decide to maintain your product registration(s), you must provide the information described in the following package within the timeframes outlined.

II. DATA COMPENSATION

As part of your application for reregistration, you must comply with the data requirements of FIFRA section 3(c)(1)(d) by including with your application a completed Data Compensation Statement (Appendix II-1). That form includes:

A. A statement that you offer to pay compensation to other persons with regard to the application to the extent required by FIFRA sections 3(c)(1)(D) and 3(c)(2)(D).

B. A statement acknowledging that if EPA approves your application for reregistration, the approval will be based on EPA's consideration of the following:

   1. All the existing "generic" data* which, according to the table, "Generic Data Requirements for Manufacturing-Use and End-Use Products" (table A at the end of Section III), is relevant to EPA's evaluation of the registrability of your product (taking into account your product's composition and formulation category, and the uses of your product which its label will permit).

   2. The "product-specific" data* which you have listed on the form entitled "Product-Specific Data Report" (Appendix II-2).

C. A statement that you have furnished an offer to pay compensation to the person(s) listed below in the manner specified:

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*/ For an explanation of the terms "generic" data and "product-specific" data, see p. 3-4 of the Registration Standard.

1. Persons to whom offers must be made: An offer must be furnished to each person who, according to the Standard, was the original submitter of any of the generic or product-specific data upon which approval of your application will be based, except that:

   a. You need not furnish an offer with respect to data that were originally submitted prior to January 1, 1970.

   b. FIFRA section 3(c)(2)(D) provides that you need not furnish an offer with respect to any "generic" data, if your product is an end-use product and if its active ingredient will be present in your product solely because of the incorporation into your product of another registered manufacturing-use product which contains that active ingredient and which you purchase from another producer. Note: This exemption does not cover "product-specific" data.

   c. Many data submitters have informed EPA that they do not wish to receive offers under FIFRA section 3(c)(1)(D). The various persons who submitted data listed in the Standard's bibliography who have not waived their rights to receive offers will be listed in tables A, B, or C. You will be required to write those companies if the data in those tables are required to support your formulations and uses.

   d. You need not furnish an offer to any person with whom you have already agreed in writing concerning the amount (if any) and terms of compensation payable under FIFRA section 3(c)(1)(D) in connection with the reregistration of your product.

   e. You need not furnish an offer with respect to any data unless the data were submitted to EPA (or its predecessor agencies) to support an application for registration, amended registration, or reregistration; to support or maintain in effect an existing registration; to support an application for an Experimental Use Permit; or to support a petition for a tolerance, food additive regulation, or other clearance under the Federal Food, Drug, and Cosmetic Act which was a prerequisite to a FIFRA registration action.

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COMPANIES THAT MAY NEED TO RECEIVE OFFERS TO PAY FOR §3(C)(1)(D)

Union Carbide Agricultural Products Company
T.W. Alexander Drive
P.O. Box 12014
Research Triangle Park, NC 27709

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2. Form of the offer: You must furnish each person who is entitled to receive an offer the following information, in writing:

   a. A notification of your intent to apply for reregistration under the Standard, and the name, active ingredient, and intended uses of your product.

   b. An offer to pay the person compensation, with respect to approval of your application, to the extent required by FIFRA sections 3(c)(1)(D) and 3(c)(2)(D), and an offer to begin negotiations to set the amount and terms of compensation.

   c. Your name, mailing address, and telephone number.

III. REQUIREMENT FOR SUBMISSION OF GENERIC DATA UNDER FIFRA SECTION 3(c)(2)(B)

A. This portion of the Guidance Package is a Notice issued under the authority of FIFRA section 3(c)(2)(B). EPA has determined that additional generic data described in this Notice must be submitted to EPA for evaluation in order to maintain in effect the registration(s) of your product(s) identified as an attachment to the cover letter accompanying this Guidance Package. As required by FIFRA section 3(c)(2)(B), you are required to take appropriate steps to comply with this Notice. EPA may suspend the registration of each of those products unless, within the specified time, you have informed EPA how you will satisfy the requirements of this Notice. Any such suspension will remain in effect until you have complied with the terms of this Notice.

B. Entitlement of Certain End-Use Registrants to An Exemption. Under the circumstances described in this section III(B), EPA will refrain from suspending the registration of an end-use product even if its registrant does not submit data in response to this Notice. EPA's position is based on the intent of Congress as set forth in FIFRA section 3(c)(2)(D). Under that section, if generic data on an active ingredient had already been submitted to EPA, an applicant for registration of an end-use product would be excused from the normal section 3(c)(1)(D) requirement of submitting or citing, and offering to pay compensation for, those data as a condition of obtaining registration. To qualify for that exemption, the active ingredient must be present in his product (during formulation or packaging) of a manufacturing-use product containing that active ingredient registered under FIFRA and purchased from another producer. The object of this provision is to simplify data compensation by making compensation for the generic data on the active ingredient an element of the market cost of registered manufacturing-use products, so that formulators or other registrants who purchase such products need not separately offer to pay for data on the active ingredient.

EPA has concluded that these principles should also apply in the closely analogous situation presented by this section 3(c)(2)(B) requirement. However, principles of fairness to those who incur expenses of data generation and submission make it necessary to ensure that a registrant be exempted from this data submission requirement only if the active ingredient in this product is being purchased from a firm which is required to submit (or to offer to share in the cost of obtaining) the generic data required by this Notice.

If a registrant who is subject to this section 3(c)(2)(B) Notice fails to comply with the data submission requirement, the Administrator may suspend his registration. However, this authority is discretionary, and the Administrator will not exercise it to suspend a registration if:

1. the registration is for an end-use product, as opposed to a manufacturing-use product; and

2. the active ingredient in the end-use product is present solely as the result of the incorporation into that product (during formulation or packaging) of a manufacturing-use product which contains that active ingredient, is registered under FIFRA, and is purchased by the registrant; and

3. the registrant completes and executes a "Generic Data Exemption Statement" (Appendix III-1) for the end-use products, and submits it to EPA within 90 days of receipt of this Notice; and

4. one or more registrants actually do undertake to submit, and do submit, all the data required by this Notice.

C. What Generic Data Must be Submitted. You may ascertain which generic data you must submit by consulting table A at the end of this section. That table shows all the generic data needed to evaluate the continued registrability of all products to which the Standard applies, and the dates by which the data must be submitted. The required data must be submitted and any necessary studies must be conducted in accordance with EPA approved protocols, The Pesticide Registration Guidelines, */ or data collected under the approved protocols of the Organization for Economic Cooperation Development (OECD) which are yet to be published. If you wish not to develop data which are necessary to support the continued registration of certain uses appearing in your current labeling, you may delete those uses at the time you submit your revised labeling for registration.

Also for certain kinds of testing (generally Ecological Effects), EPA requires the test substance to be a "typical formulation," and that in those cases EPA needs data of that type for each major formulation category (e.g., emulsifiable concentrates, wettable powders, granulars, etc.). These are classified as generic data and, when needed, are specified in table A. EPA may possess data on certain "typical formulations" but not others. Note: The "typical formulation" data should not be confused with product-specific data which are required on each formulation, regardless of type of formulation. Product-specific data are further explained under Section IV of this document and are specified in tables B and C at the end of this Section.

D. Options Available for Complying With Requirements to Submit Data.

You must submit to EPA within 90 days of your receipt of this Notice a completed copy of the form entitled "FIFRA §3(c)(2)(B) Summary Sheet" (Appendix III-2) for each of your products. On that form you must state which of the following methods you will use to comply with the requirements of this Notice:

1. Attach a completed "Generic Data Exemption Statement" (Appendix III-1).

2. (a) Notify EPA that you will submit the data, and

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*/ The Pesticide Registration Guidelines were proposed in two separate publications. On July 1, 1978, EPA issued proposed guidelines for product chemistry, environmental chemistry, and fish and wildlife hazard testing, 43 FR 29696. The Agency published proposed human hazard guidelines on August 22, 1978, 43 FR 37336.

(b) either submit the existing data you believe will satisfy the requirement, or state that you will generate the data by conducting testing. If the test procedures you will use deviate from (or are not specified in) the Registration Guidelines or protocols contained in the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must enclose the protocols you use.

3. Notify EPA that you have entered into an agreement with one or more other registrants to jointly develop (or share in the cost of developing) the data. If you elect this option you must at the same time notify EPA which registrant(s) are parties to the agreement. At least one of the parties to the agreement must respond to this Notice in the manner specified by paragraph III (D)(1) above.

4. File with EPA a completed "Statement of Willingness to Enter Into An Agreement With Other Registrants for Development of Data" (Appendix III-3) */.

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*/ FIFRA section 3 (c)(2)(B) authorizes joint development of data by two or more registrants, and provides a mechanism by which parties can obtain an arbitrator's decision if they agree to jointly develop data but fail to agree on all the terms of the agreement. The statute does not compel any registrant to agree to develop data jointly.

In EPA's opinion, joint data development by all registrants who are subject to the requirements to submit a pertinent item of data, or a cost-sharing agreement between all such registrants, is clearly in the public interest. Duplication of testing could increase costs, tie up testing facilities, and subject an unnecessarily large number of animals to testing.

As noted earlier, EPA has discretion not to suspend the registration of a product when a registrant fails to submit data required under FIFRA section 3(c)(2)(B). EPA has concluded that it is appropriate to exercise its discretion not to suspend in ways which will discourage duplicative testing. Accordingly, if: (1) a registrant has informed us of his intent to develop and submit data required by this Notice; and (2) a second registrant informs EPA that it has made a bona fide offer to the first registrant to share in the expenses of the testing [on terms to be agreed upon or determined by arbitration under FIFRA section 3(c)(2)(B)(iii)] and (3) the first registrant has declined to agree to enter into a cost-sharing agreement, EPA will not suspend the second firm's registration. While the first firm is not required to agree to jointly develop data, EPA is not required to force the second firm to engage in economically inefficient duplicative testing in order to maintain its registration.

5. Request that EPA amend your registration by deleting the uses for which the data are needed.

6. Request voluntary cancellation of the registration(s) of your products for which the data are needed.

E. Procedures for Requesting Changes In Testing Methodology and Extensions of Time

EPA recognizes that you may disagree with our conclusions regarding the appropriate ways to develop the required data or how quickly the data must be submitted.

If the test procedures you plan to use deviate from (or are not specified in) registration guidelines or protocols contained in the reports of the Expert Groups to the Chemical Groups, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit the protocol for Agency review prior to the initiation of the test.

If you want, or think that you will need, more time to generate the required data than is allowed by EPA's schedule, you may submit a request for an extension of time. The extension request must be submitted in writing to the Product Manager. The extension request should state the reasons why you conclude that an extension is appropriate. You must strive to meet the deadline for submitting the required data while EPA considers your request.

TABLE A

GENERIC DATA REQUIREMENTS FOR MANUFACTURING-USE AND END-USE PRODUCTS CONTAINING NAPHTHALENEACETIC ACID, ITS SALTS, ESTER, AND ACETAMIDE

Guideline Citation	Name of Test	Use Pattern	Must Applicant Acknowledge Reliance Under FIFRA 3(c)(1)(D)?	Bibliographic Citation	Must Data Be Submitted Under FIFRA 3(c)(2)(B)?	Months Allowed Before Submission
Toxicology						
A. Naphthaleneacetic Acid						
163.81-1	Acute Oral Toxicity	All Uses	No		Yes	6 Months
163.81-2	Acute Dermal Toxicity	All Uses	No		Yes	6 Months
163.81-3	Acute Inhalation Toxicity	All Uses	No		Yes	6 Months
163.81-4	Primary Eye Irritation	All Uses	No		Yes	6 Months
163.81-5	Primary Skin Irritation	All Uses	No		Yes	6 Months
163.81-6	Dermal Sensitization	All Uses	No		Yes	6 Months
163.82-1	Subchronic Oral Toxicity	Food Uses	Yes	GS0023002, GS0023001[a] 005008106, GS0023031[a]	No	13 Months
163.83-3	Teratogenicity	All Uses	Yes	GS0023044[a]	Yes	
163.84-2 through 4	Mutagenicity	All Uses	Yes	005008826, GS0023037[a] GS0023038[a], GS0023039[a] GS0023040[a], GS0023041[a] GS0023042[a], GS0023043[a]	No	
163.85-1	Metabolism (Identification of Metabolites)	All Uses	Yes	000004942, 005008052	No	

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[a] Union Carbide Agricultural Products Company, Inc.; T.W. Alexander Drive; P.O. Box 12014; Research Triangle Park, NC 27709

Toxicology

B. Naphthaleneacetic Acid, Ammonium Salt

Citation	Name of Test	Use Pattern	FIFRA 3(c)(1)(D)?	Citation	FIFRA 3(c)(2)(B)?	Before Submission
163.81	Acute Toxicity Testing[1]	All Uses				
163.81-4	Primary Eye Irritation	All Uses	No		Yes	5 Months

In addition to the above data that must be provided for the fulfillment of the requirements for the ammonium salt, the data on NAA will be considered for manufacturing-use products containing the ammonium salt.

C. Naphthaleneactic Acid, Sodium & Potassium Salts

The data for NAA will be considered for manufacturing-use products containing the sodium and potassium salts.

D. Naphthaleneacetic Adid, Ethyl Ester

Citation	Name of Test	Use Pattern	FIFRA 3(c)(1)(D)?	Citation	FIFRA 3(c)(2)(B)?	Before Submission
163.81-1	Acute Oral Toxicity	All Uses	Yes	GS0023048[a]	No	
163.81-2	Acute Dermal Toxicity	All Uses	Yes	GS0023047[a]	No	
163.81-3	Acute Inhalation Toxicity			GS0023046[a]	No	
163.81-4	Primary Eye Irritation	All Uses	Yes	GS0023045[a]	No	

In addition to the above data that must be provided for the fulfillment of the requirements for the ethyl ester, the data on NAA will be considered for manufacturing-use products containing the ethyl ester.

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[1] The requirements for these tests will be determined once acute toxicity data are available for NAA.

[a] Union Carbide Agricultural Products Company, Inc.; T.W. Alexander Drive; P.O. Box 12014; Research Triangle Park, NC 27709

TABLE A (Continued)

GENERIC DATA REQUIREMENTS FOR MANUFACTURING-USE AND END-USE PRODUCTS
CONTAINING NAPHTHALENEACETIC ACID, ITS SALTS, ESTER, AND ACETAMIDE

Guideline Citation	Name of Test	Use Pattern	Must Applicant Acknowledge Reliance Under FIFRA 3(c)(1)(D)?	Bibliographic Citation	Must Data Be Submitted Under FIFRA 3(c)(2)(B)?	Months Allowed Before Submission
Toxicology						
E. **Naphthaleneacetamide**						
The data for NAA will be considered for manufacturing-use products containing the acetaminde for NAA.						
Residue Chemistry						
	Metabolism in Plants	Food Uses	Yes	000004943, 005009196	No	
	Metabolism in Animals	Food Uses	Yes	005007966, 005008070, 000004942, 005008052, 005008057	No	
	Analytical Methods	Food Uses	Yes	000004943, 000004916 005007967, 005020083, 000004946, 005002768, 005008121, 005008068, GS00223012[a], GS0023019[a], GS0023036[a]	No	
	Residue Data: Crops - Apples, Pears, Pineapplies, Olives	Food Uses	Yes	000004943, GS00023012[a], GS0023019[a], GS0023036[a]	Yes[2]	18 Months

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[a] Union Carbide Agricultural Products Company, Inc.; T.W. Alexander Drive; P.O. Box 12014; Research Triangle Park, NC 27709

[2] Degradation data indicate that residues in plants of ester, salts, and acetamide of NAA degrade rapidly residues of NAA and that these residues are of the same order of magnitude as those for NAA. Additional data are required to confirm the degradation of these chemicals.

TAB' ' (Continued)

GENERIC DATA REQUIREMENTS FOR MANUFACTURING-USE AND END-USE PRODUCTS CONTAINING NAPHTHALENEACETIC ACID, ITS SALTS, ESTER, AND ACETAMIDE

Guideline Citation	Name of Test	Use Pattern	Must Applicant Acknowledge Reliance Under FIFRA 3(c)(1)(D)?	Bibliographic Citation	Must Data Be Submitted Under FIFRA 3(c)(2)(B)?	Months Allowed Before Submission
	Dissociation Data	Food Uses	No		Yes[3]	12 Months
Ecological Effects						
163.71-1	Avian Single-Dose Oral LD_{50}	All Uses	Yes	GS0023023[a], GS0023021[a]	No	
163.71-2	Avian Dietary LC_{50}	All Uses	Yes	GS0023025[a], GS0023025[a]	No	
163.72-1	Fish Acute LC_{50}	All Uses	Yes	GS0023022[a], GS0023051[a]	Yes	6 Months
163.72-2	Acute Toxicity To Aquatic Invertebrates	All Uses	Yes	GS0023050[a]	Yes	6 Months
163.122-1	Seed Germination	All Uses	Yes	005010399, 005012526	No	
163.122-1	Vegetative Vigor	All Uses	Yes	005007254, 005007255	No	
163.122-1	Effects on Terrestrial Macrophytes	All Uses	No		Yes	6 Months
163.122-2	Effects on Aquatic Macrophytes	All Uses	No		Yes	6 Months
163.122-2	Effects on Algae	All Uses	No		Yes	6 Months

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[a] Union Carbide Agricultural Products Company, Inc.; T.W. Alexander Drive; P.O. Box 12014; Research Triangle Park, NC 27709

[3] Data on the dissociation or hydrolyzation of these chemicals must be submitted.

TABLE B

PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE AND END-USE PRODUCTS CONTAINING NAPHTHALENEACETIC ACID, ITS SALTS, ESTER, AND ACETAMIDE

Guideline Citation	Name of Test	Composition Characteristics	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Data Be Submitted Under FIFRA 3(c)(2)(B)?	Months Allowed Before Submission
PRODUCT CHEMISTRY						
163.61-3	Product Identity and Disclosure of Ingredients	Each Product	No		Yes[1]	6 Months
163.61-4	Description of Manufacturing Process	Each Product	No		Yes[2]	6 Months
163.61-5	Discussion on Formulation of Unintentional Ingredients	Each Product	No		Yes	6 Months
163.61-6	Declaration and Certification of Ingredients Limits	Each Product	No		Yes[3]	6 Months
163.61-7	Product Analytical Methods and Data	Each Product	No		No	
163.64	Physical and Chemical Properties	Technical Grade of AI and Each Product	No		Yes	6 Months

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[1] All impurities and inerts in the technical chemicals produced by or for Greenwood Company, Millmaster Onyx Corporation, and Aceto Chemical Company must be identified. Formulation of all other technical products and chemicals covered by this Standard must be identified.

[2] Complete information must be supplied by each manufacturer on the present manufacturing process, including data listed in 43 FR 29709.

[3] The upper and lower limits of each active and inert ingredient in manufacturing-use and end-use products must be declared and certified. The upper limit for each impurity, reaction product, and degradation product must be provided. If not already cleared, all inert ingredients contained in products with food uses must be cleared by the registrant with the Food and Drug Administration.

TABLE C

PRODUCT-SPECIFIC DATA REQUIREMENTS
FOR AND END-USE PRODUCTS
CONTAINING NAPHTHALENEACETIC ACID, ITS SALTS, ESTER, AND ACETAMIDE

Guideline Citation	Name of Test	Composition Characteristics	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Data Be Submitted Under FIFRA 3(c)(2)(B)?	Months Allowed Before Submission
PRODUCT CHEMISTRY						
163.61-3	Product Identity and Disclosure of Ingredients	Each Product	No		Yes	6 Months
163.61-4	Description of Manufacturing Process	Each Product	No		Yes[1]	6 Months
163.61-5	Discussion on Formulation of Unintentional Ingredients	Each Product	No		Yes	6 Months
163.61-6	Declaration and Certification of Ingredients Limits	Each Product	No		Yes[2]	6 Months
163.61-7	Product Analytical Methods and Data	Each Product	No		No	
163.64	Physical and Chemical Properties	Each Product	No		Yes	6 Months

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[1] Complete information must be supplied by each manufacturer on the present manufacturing process, including data listed in 43 FR 29709.

[2] The upper and lower limits of each active and inert ingredient in manufacturing-use and end-use product must be declared and certified. The upper limit for each impurity, reaction product, and degradation product must be provided. If not already cleared, all inert ingredients contained in products with food uses must be cleared by the registrant with the Food and Drug Administration.

TABLE C (Continued)

PRODUCT-SPECIFIC DATA REQUIREMENTS
FOR END-USE PRODUCTS
CONTAINING NAPHTHALENEACETIC ACID, ITS SALTS, ESTER, AND ACETAMIDE

Guideline Citation	Name of Test	Composition Characteristics	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Data Be Submitted Under FIFRA 3(c)(2)(B)?	Months Allowed Before Submission
Toxicology						
Soluble Concentrates						
A. Naphthaleneacetic Acid						
163.81-4	Primary Eye Irritation	Each Formulation or Substantially Similiar Formulations Containing > 50% Diacetone or Petroleum Oil	No		Yes	6 Months
B. Potassium Salt of Naphthaleneacetic Acid						
163.81-4	Primary Eye Irritation	Each Formulation or Substantially Similiar Formulations Containing > 50% Diacetone or Petroleum Oil	No		Yes	6 Months
C. Naphthaleneacetic Acid, Ethyl Ester						
163.81-1	Acute Oral Toxicity	Each Formulation or Substantially Similar Formulations	Yes	GS0023035[a]	No	
163.81-2	Acute Dermal Toxicity	Each Formulation or Substantially Similar Formulations	Yes	GS0023032[a]	No	

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[a] Union Carbide Agricultural Products Company, Inc., T.W. Alexander Drive; P.O. Box 12014; Research Triangle Park, NC 27709.

TABLE C (C ued)

PRODUCT-SPECIFIC DATA REQUIREMENTS
FOR END-USE PRODUCTS
CONTAINING NAPHTHALENEACETIC ACID, ITS SALTS, ESTER, AND ACETAMIDE

Guideline Citation	Name of Test	Composition Characteristics	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Data Be Submitted Under FIFRA 3(c)(2)(B)?	Months Allowed Before Submission
163.81-3	Acute Inhalation Toxicity	Each Formulation or Substantially Similar Formulations	Yes	GS0023034[a]	No	
163.81-1	Primary Eye Irritation	Each Formulation or Substantially Similar Formulations	Yes	GS0023033[a]	No	
D. Naphthaleneacetamide						
163.81-4	Primary Eye Irritation	Each Formulation or Substantially Similar Formulations Containing > 50% Isopropanol and Fertilizer	No		Yes	6 Months

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[a] Union Carbide Agricultural Products Company, Inc., T.W. Alexander Drive; P.O. Box 12014; Research Triangle Park, NC 27709.

IV. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA UNDER FIFRA §3(c)(2)(B)

A necessary first step in determining which statements must appear on your product's label is the completion and submission to EPA of product-specific data to fill "gaps" identified by EPA concerning your product. Under the authority of FIFRA section 3(c)(2)(B) EPA has determined that you must submit these data to EPA in order to maintain the registration of your product(s). All these data must be submitted not later than 6 months after you receive this Guidance Package.

The tables entitled "Product-Specific Data Requirements for Manufacturing-Use Products" and "Product-Specific Data Requirements for End-Use Products," which appear as tables B and C of this Guidance Package, permit you to determine which product-specific data you must submit. This can be done by examining the entries in the column of those tables entitled "Must Data Be Submitted Under §3(c)(2)(B)."

In some cases the tables may note that EPA already possesses some or all of the product-specific data needed to evaluate your product; if that is the case, we encourage you to elect to cite that data in lieu of generating and submitting new data. (You must comply with FIFRA section 3(c)(1)(D) if you elect to cite existing data; see section II of this Guidance Package.)

The tables also indicate that in some cases, a product-specific data requirement for a group of similar products can be satisified by a single test.

Your application for registration must include a completed copy of the form entitled "Product-Specific Data Report" (Appendix II-2), stating the methods you are using to comply with the product-specific data requirements.

V. LABELING, CLASSIFICATION, AND PACKAGING INFORMATION

The Agency has determined to require applicants for registration to amend their product's labeling to ensure that each label (1) contains accurate, complete, and sufficient instructions and precautions, reflecting the results of data concerning the product and its ingredients, and (2) incorporates labeling format and terminology which are sufficiently standardized to avoid user confusion.

As part of your application for reregistration, you must submit draft labeling revised to be consistent with: your product-specific data; the precautionary statements and use directions, and the regulations concerning classification

[40 CFR §162.11(c)], packaging [40 CFR §162.16], and labeling [40 CFR §162.10], as indicated by the following paragraphs of this section of the Guidance Package. The labeling must be submitted within 6 months of your receipt of this Guidance Package.

If you fail to submit revised labeling and packaging information complying with this section, EPA will issue a notice of intent to cancel your registration under FIFRA §6(b)(1).

A. Label Contents

40 CFR Section 162.10 (Appendix V-1) requires that certain specific labeling statements must appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to tables D, E, and F (Appendix V-2).

Item 1. PRODUCT NAME - The name, brand, or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading. See Appendix V-1. [40 CFR §162.10(b)].

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text. See Appendix V-1. [40 CFR §162.10(c)].

Item 3. NET CONTENTS - A net content statement is required on all labels. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net content must be stated in terms of weight, expressed as avoirdupois pounds and ounces, and stated in terms of the largest suitable unit, i.e., "1 pound 10 ounces" rather than "26 ounces." In addition to the required units specified, net contents may be expressed in metric units. See Appendix V-1. [40 CFR §162.10(d)].

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. See Appendix V-1. [40 CFR §162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container. See Appendix V-1. [40 CFR §162.10(f)]

Item 6. INGREDIENT STATEMENT - An ingredient statement is required on the front panel and must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredient statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. See Appendix V-1. [40 CFR §162.10(g)]

Item 6A. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - All labels are required to have precautionary statements grouped together on the front panel, preferably within a block outline. The table below shows the minimum type size requirements on various sized labels, as set forth in the Regulations. It should be noted that labeling regulations now being drafted require a minimum 8 point (3 mm) type size for all print on a label. When the guidelines are finalized, the below list may be modified accordingly.

Size of Label on Front Panel in Square Inches	Signal Word As Required Minimum Type Size All Capitals	"Keep out of Reach of Children" as Required
5 and under	6 point	6 point
above 5 to 10	10 point	8 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - All labels are required to have the statement "Keep Out of Reach of Children" located on the front panel above the signal word except where contact with children during distribution or use is unlikely. See Appendix V-1. [40 CFR §162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (Caution, Warning, or Danger) is required on the front panel immediately below the child hazard warning statement. See Appendix V-1. [40 CFR §162.10(h)(1)(i)]

Item 7C. SKULL AND CROSSBONES AND WORD "POISON" - On products assigned toxicity category I on the basis of oral, inhalation, or dermal toxicity the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word poison. See Appendix V-1. [40 CFR §162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity categories I, II, and III. See Appendix V-1. (40 CFR §162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or back) Panel for Additional Precautionary Statement" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. See Appendix V-1. [40 CFR §162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements as listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. See Appendix V-1. [40 CFR §162.10(h)(2)]

Item 8A. HAZARDS TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure, and the precautions taken to avoid accident, injury, or damage. See Appendix V-1. [40 CFR §162.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to nontarget organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. See Appendix V-1. (40 CFR §162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD

1. Flammability statement. Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in Appendix V-3. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

2. Criteria for declaration of nonflammability. The following criteria will be used to determine if a product in nonflammable:

   a. A "nonflammable gas" is a gas (or mixture of gases) that will not ignite when a lighted match is placed against the open cylinder valve.

   b. A "nonflammable liquid" is one having a flashpoint greater than 350 °F (177 °C) as determined by the method specified in 40 CFR §163.61-8(c)(13)(ii) of Subpart D.

   c. A "nonflammable aersol" is one which meets the following criteria:

      i. The flame extension is zero inches, using the method specified in 40 CFR §163.61-8(c)(13)(ii);

      ii. There is no flashback; and

      iii. The flashpoint of the nonvolatile liquid component is greater than 350 °F (177 °C), determined by the method specified in 40 CFR §163.61-8(c)(13)(i).

3. Declaration of nonflammability. Products which meet the criteria for nonflammability specified above may bear the item "nonflammable" or "nonflammable (gas, liquid, etc.)" on the label.

   It may appear as a substatement to the ingredients statement, or on a back or side panel, but shall not be highlighted or emphasized (as with an inordinately large type size) that may detract from precaution.

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4. Other physical/chemical hazard statements. When chemistry data submitted in accordance with 40 CFR §163.61-10(c) demonstrate hazard of a physical or chemical nature other than flammability, appropriate statements of hazard will be prescribed. Such statements may address hazards or explosivity, oxidizing or reducing capability, or mixing with other substances to produce toxic fumes.

Item 9. PRODUCT CLASSIFICATION: CLASSIFICATION LABELING REQUIREMENTS AND COMPLIANCE SCHEDULE - Section 3(d) of FIFRA requires that all pesticide formulations/uses be classified for either general or restricted use, and that those uses classified as restricted be limited to use by certified applicators or persons under their direct supervision (or subject to such other restrictions as may be imposed by regulation).

In Chapter 2 of the Registration Standard, the Agency has: (1) indicated certain formulations/uses to be restricted based either on a previous classification determination made through the optional procedures of 40 CFR §162.30 or based on data already available to the Agency, or (2) indicated certain formulations/uses to be unrestricted based on data already available to the Agency, or (3) reserved any classification decision until appropriate short-term data are submitted. Uses have not been classified for general use at this time because such a decision requires an evaluation of chronic data most of which have yet to be generated.

The product-specific data required by the Standard should be used by each registrant to make a classification determination following the criteria of 40 CFR §162.11(c) (Appendix V-4). The draft label(s) submitted to the Agency as part of your application should reflect this determination and must be consistent with the terms of 40 CFR §162.10 and this guidance package with respect to label language and format for restricted use products. (No label changes with respect to classification are required for products with unrestricted uses.) The rationale supporting a classification proposal by the registrant that differs from a classification determination found in the Standard should be submitted with your application.

During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of §162.11(c). You will be notified of the Agency's classification evaluation.

A. Classification Labeling Requirements

1. Unrestricted Uses - No label changes with respect to a classification statement are necessary for those formulations/uses that are unrestricted.

2. Restricted Uses - Pesticide products bearing directions for use for formulations/uses classified restricted shall bear statements of restricted use classification on the front panel as described below:

   a. Front panel statement of restricted use classification.

      i. At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in 40 CFR §162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement, "Restricted Use Pesticide" shall appear.

      ii. Directly below this statement on the front panel, a summary statement of the terms of restriction shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

3. Some But Not All Uses Restricted - If you determine that some uses should be classified RESTRICTED and some uses should be unrestricted, several courses of action detailed below are available:

   i. You may delete all RESTRICTED uses and submit a draft label of the registration of your product to reflect only those uses that are unrestricted.

   ii. Unrestricted uses may appear on a RESTRICTED label, but not vice versa. Therefore, you have the option of using a RESTRICTED USE label bearing all of your directions for use. If you choose this option, you may not distinguish those uses that are not unrestricted from those that are RESTRICTED.

iii. You may register two separate products with identical formulations, one containing only unrestricted uses and the other RESTRICTED uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the product names will be assigned separate registration numbers.

B. Compliance Schedules

1. Unclassified uses - None.

2. Restricted uses - The compliance schedule for restricted use products begins only after the approved label is returned to you as follows:

   a. No product with a use classified for restricted use under this first phase of reregistration may be released for shipment by the registrant or producer after the 120th day after the date of acceptance of the label submitted in conjunction with your application, unless such product bears the new accepted label or has supplemental labeling affixed or is accompanied by supplemental labeling. For the purposes of the first phase of reregistration, supplemental labeling means:

      i. an adhesive sticker containing the restricted use statement specified in 40 CFR 162.10(j)(2) and also found in this section;

      ii. a separate form containing the product name as it appears on the restricted use statement specified in 40 CFR §162.10(j)(2) and also found in this section, and

      iii. the approved new label.

   b. No product with a use classified for restricted use under this first phase of reregistration may be distributed or sold by retailers or other persons after the 270th day after the acceptance of the label submitted in conjunction with your application, unless such product bears the new accepted label or has supplemental labeling affixed or is accompanied by supplemental labeling.

c. No product with a use classified for restricted use under this first phase of reregistration may be released for shipment by the registrant or producer after the 270th day after the acceptance of the label submitted in conjunction with your application, unless such product bears the new accepted label.

d. In cases where a registrant chooses to delete product uses classified as restricted under the first phase of reregistration, no such product may be released for shipment by the registrant or producer after the 180th day after acceptance of the label submitted in conjunction with your application, unless such product bears the new accepted label.

e. No product with a use classified as restricted under this first phase of reregistration may be advertised without including the restricted use classification after the 120th day after the acceptance of the label submitted in conjunction with your application.

Brochures, technical phamphlets, and similar material which are in final printed form on the date of acceptance of the new label may be distributed only for 270 days from the date of acceptance.

Item 9C. MISUSE STATEMENT - The following statement is required on your label: It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Appendix V-1. [40 CFR §162.10(l)(2)(ii)]

Item 10A. REENTRY STATEMENT - If there is a reentry statement for your product, that statement will be set forth in the second chapter of the Standard.

Item 10C. STORAGE and DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. Make certain that the statement you use pertains specifically to your product. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix V-5 of the latest specific storage and disposal product labels.

Item 10D. DIRECTION FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. See Appendix V-5 [40 CFR §162.10]

B. Collateral Information

Bulletins, leaflets, circulars, brochures, data sheets, flyers, and other graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. They should be made part of the response to this Notice and submitted for review.

C. Special (Child Resistant) Labeling Requirements

As required in 40 CFR 162.16 (Appendix V-6), any pesticide that is released for shipment by the registrant after March 9, 1981, must be in special packaging if:

(1) its labeling permits residential use;

(2) it has not been classified for restricted use; and

(3) it meets the toxicity criteria of 40 CFR 162.12(c)(2).

Additional information on child resistant packaging is being developed and will be mailed to you shortly.

VI. INSTRUCTION FOR SUBMISSION

All applications prepared in response to this Notice should be addressed as follows:

Product Manager Robert J. Taylor
(703) 557-1800
Registration Division (TS-767)
Office of Pesticide Programs
Environmental Protection Agency
Washington, DC 20460

For each affected product for which continued registration is desired, you must:

A. Within 90 days from receipt of this package you must submit the "FIFRA" Section (3)(c)(B) Summary Sheet (Appendix III-2) with appropriate attachments.

B. Within 6 months from receipt of this package you must submit:

   1. "Application for Amended Pesticide Registration" (EPA Form 8570-11).

   2. "Confidential Statement of Formula" (EPA Form 8570-4).

   3. "Data Compensation Statement: Reregistration" (Appendix II-1).

   4. Product Specific Data Report (Appendix II-2).

   5. Two copies of any required product-specific data.

   6. Two copies of draft labeling, including the label and associated brochures. If the current accepted labeling conforms to the requirements of the guidance package and the results of the short-term data, the registrant can submit such labeling. Otherwise, the labeling should be in draft form. The draft labeling should be either typewritten text on 8 1/2 x 11 inch paper or a mock-up of the labeling suitable for storage in 8 1/2 x 11 inch files. The draft label must indicate the intended colors of the final label, clear indication of the front and side panels, and the intended type sizes of the text.

   7. A progress report on the development of generic mid-term and long-term data.

C. Within 24 months from the receipt of this package you must submit:

   1. All required generic midterm data (table A).

   2. A progress report on the development of generic long-term data (table A).

D. Within 42 months from the receipt of this package you must submit the generic long-term data as committed (table A).

Note: If for any reason any required test is delayed or aborted so that meeting the agreed submission time will be delayed, notify the Product Manager listed above.

VII. STATEMENT ON AGENCY POSITION REGARDING COURT SUITS INVOLVING FIFRA SECTION 3(c)(1)(D)

Several companies have sued EPA in an attempt to block implementation of FIFRA section 3(c)(1)(D), which allows EPA to consider one firm's data in support of reregistration of another firm's product. EPA considers all available generic data in preparing a Registration Standard. If the companies are successful in the litigation, they could then use the reregistration process as a means of forcing competitors off the market. EPA does not intend to allow the reregistration requirement to be distorted in this fashion. If your application for reregistration would be affected by this litigation, you will receive further instructions from EPA before the time your application must be submitted to EPA.

DATA COMPENSATION STATEMENT: REREGISTRATION

EPA Reg. No.: ______________________________

Product Name: ______________________________

Applicant's Name & Address: ______________________________

____

____

Date of application for reregistration: ______________________________

Registration Standard for products containing: ______________________________

Date Reregistration Standard Issued: ______________________________

Date Reregistration Guidance Package Issued: ______________________________

In connection with applicant's application for reregistration under the Registration Standard and Guidance Package identified above:

(A) Applicant offers to pay compensation to other persons to the extent required by sections 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended.

(B) Applicant understands and acknowledges that if EPA approves the application, the approval will be based solely on EPA's consideration of:

(1) All the generic data which, according to the Registration Standard and Guidance Package identified above, were found relevant to EPA's evaluation of the registrability of applicant's product (taking into account the product's composition and formulation category, and the uses its label will permit); and

(2) The product-specific data listed on the form entitled "Product-Specific Data Report" which is part of this application.

(3) Applicant states that offers to pay compensation have been furnished to the persons and in the form specified by the Guidance Package identified above.

Date: ______________________________

Name of registrant's
authorized representative: ______________________________
(signature)

____
(typed)

PRODUCT-SPECIFIC DATA REPORT

Appendix II-2

EPA Registration No. ____________

Reg. Std. for ____________
Data Reg. Std. Issued: ____________
Guidance Package Date: ____________

Registration Guideline No.	Name of Test	Test not required for my Product Listed Above (check below)	I am complying with Data Requirements By		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID #	Submitting Data (attached) (check below)	
163.61-3	Product identity and disclosure ingredients				
-4	Description of manufacturing process				
-5	Discussion on formation of unintentional ingredient				
-6	Declaration and certification of ingredient limits				
-7	Product analytical methods and data				
163.61-4(1)	Color				
-4(2)	Odor				
-4(3)	Melting point				
-4(4)	Solubility				
-4(5)	Stability				
-4(6)	Octanol/water partition coefficient				
-4(7)	Physical state				
-4(8)	Density or specific gravity				
-4(9)	Boiling Point				
-4(10)	Vapor Pressure				
-4(11)	pH				
-4(12)	Storage stability				
-4(13)	Flammability				
-4(14)	Oxidizing or reducing action				
-4(15)	Explosiveness				
-4(16)	Miscibility				
-4(17)	Viscosity				
-4(18)	Corrosion characteristics				
-4(19)	Dielectric breakdown voltage				
163.71-5(1)	Cage or pen field test				
-5(2)	Full-scale field test				
163.72-1	Fish acute LC_{50}--rainbow trout and bluegill				
-2	Acute toxicity to aquatic invertebrates				
-3	Acute toxicity to estuarine and marine organisms				
-6(a)(1)	Short-term simulated field test				
-6(a)(2)	Long-term simulated field test				
163.61-1	Acute oral toxicity				
-2	Acute dermal toxicity				
-3	Acute inhalation toxicity				
-4	Primary eye irritation				
-5	Primary dermal irritation				
-6	Dermal sensitization				

Appendix III-1

GENERIC DATA EXEMPTION STATEMENT

EPA Product Registration Number: ______________________________

Registrant's Name: ______________________________

As an authorized representative of the registrant of the product identified above, I hereby certify that:

(1) I have read and am familiar with the terms of a Notice in a Guidance Package from EPA dated ________ concerning a requirement for submission under FIFRA section 3(c)(2)(B).

(2) My firm requests that EPA not suspend the registration of our product, despite our lack of intent to submit the data in question, on the grounds that the product is an end-use product and it contains the active ingredient solely as the result of the incorporation into the product (during formulation or packaging) of a manufacturing-use product which contains that active ingredient, which is registered under FIFRA section 3, and which is purchased by us from another producer.

(3) An accurate Confidential Formula Statement for the above-identified product, is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient in my firms's product. My firm will apply for an amendment to the registration prior to changing the source of the active ingredient in our product.

(4) I understand, and agree on behalf of my firm, that if at any time any portion of this Statement is no longer true, or if my firm fails to comply with the undertaking made in this Statement, my firm's product's registration may be suspended in accordance with FIFRA section 3(c)(2)(B).

Dated: ________________

Registrant's Authorized
Representative:

____
(Signature)

____
(Typed)

FIFRA §3(C)(2)(B) SUMMARY SHEET

EPA Registration No.: ______________________
Product Name: ______________________
Applicant's Name: ______________________
Registration Standard for Products Containing: ______________________
Date Registration Standard Issued: ______________________
Date Guidance Package Issued: ______________________

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(c)(2)(B) notice contained in the referenced Guidance Package, I am responding in the following manner:

1. ☐ Attached is a completed "Generic Data Exemption Statement."

2. ☐ I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use.

3. ☐ I have entered into an agreement with one or more other registrants under FIFRA §3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by (name of other registrant).

4. ☐ I enclose a completed "Statement of Willingness to Enter Into An Agreement With Other Registrants for Development of Data" with respect to the following data requirements:

5. ☐ I request that you amend my registration by deleting the following uses:

6. ☐ I request voluntary cancellation of the registration of this product.

Dated: ______________

Registrant's Authorized
Representative:

____
(Signature)

____
(Typed)

STATEMENT OF WILLINGNESS TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(1) I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA section 3(c)(2)(B) contained in a Guidance Package dated ________________ to submit data concerning the active ingredient ____________________________________:

Name of Firm	EPA Company Number

(This firm or group of firms is referred to below as "my firm").

(2) My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

(3) My firm has offered in writing to enter into such an agreement, and has offered to be bound by an arbitration decision under FIFRA section 3(c)(2)(B)(iii) if agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

Firm	Date of offer

However, none of those firm(s) accepted my offer.

(4) My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit the data to avoid suspension of its registration(s) under FIFRA section 3(c)(2)(B).

Dated: ________________________ ________________________

(Signature)

____

(Typed)

§ 162.10 Labeling requirements.

(a) *General*—(1) *Contents of the label.* Every pesticide products shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) *Prominence and legibility.* (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) *Language to be used.* All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) *Placement of Label*—(i) *General.* The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) *Tank cars and other bulk containers*—(A) *Transportation.* While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170–189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) *Storage.* When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) *False or misleading statements.* Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) *Final printed labeling.* (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) *Name, brand, or trademark.* (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for * * *," "Distributed by * * *," or "Sold by * * *" to show that the name is not that of the producer.

(d) *Net weight or measure of contents.* (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68° F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) *Product registration number.* The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) *Producing establishments registration number.* The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) *Ingredient statement*—(1) *General.* The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) *Position of ingredient statement.* (i) The ingredient statement is normally required on the front panel of

the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) *Names to be used in ingredient statement.* The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) *Statements of percentages.* The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) *Accuracy of stated percentages.* The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) *Deterioration.* Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) *Inert ingredients.* The Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) *Warnings and precautionary statements.* Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups: those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) *Required front panel statements.* With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD$_{50}$	Up to and including 50 mg/kg.	From 50 thru 500 mg/kg	From 500 thru 5000 mg/kg.	Greater than 5000 mg/kg.
Inhalation LC$_{50}$	Up to and including .2 mg/liter.	From .2 thru 2 mg/liter	From 2. thru 20 mg/liter.	Greater than 20 mg/liter.
Dermal LD$_{50}$	Up to and including 200 mg/kg.	From 200 thru 2000	From 2,000 thru 20,000.	Greater than 20,000.

Hazard indicators	Toxicity categories			
	I	II	III	IV
Eye effects	Corrosive; corneal opacity not reversible within 7 days.	Corneal opacity reversible within 7 days; irritation persisting for 7 days.	No corneal opacity; irritation reversible within 7 days.	No irritation.
Skin effects	Corrosive	Severe irritation at 72 hours.	Moderate irritation at 72 hours.	Mild or slight irritation at 72 hours.

(i) *Human hazard signal word—(A) Toxicity Category I.* All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) *Toxicity Category II.* All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) *Toxicity Category III.* All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) *Toxicity Category IV.* All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) *Use of signal words.* Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) *Child hazard warning.* Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) *Statement of practical treatment—(A) Toxicity Category I.* A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) *Other toxicity categories.* The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) *Placement and prominence.* All the require front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Required signal word, all capitals	"Keep out of reach of Children"
	Points	Points
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) *Other required warnings and precautionary statements.* The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) *Hazard to humans and domestic animals.* (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Front panel statement of practical treatment required.]	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.]	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.]
III	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.]	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV	[No precautionary statements required.]	[No precautionary statements required.]

(ii) *Environmental hazards.* Where a hazard exists to non target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

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(iii) *Physical or chemical hazards.* Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

(A) Pressurized Containers	
Flash point at or below 20° F; if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
Flash point above 20° F and not over 80° F or if the flame extension is more than 18 in long at a distance of 6 in from the flame.	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
(B) Nonpressurized Containers	
Flash point	*Required text*
At or below 20° F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20° F and not over 80° F	Flammable. Keep away from heat and open flame.
Above 80° F and not over 150° F	Do not use or store near heat or open flame.

(i) *Directions for Use*—(1) *General requirements*—(i) *Adequacy and clarity of directions.* Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) *Placement of directions for use.* Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular:" and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use*—(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(*1*) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(*2*) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(*3*) The product will not come into the hands of the general public except after incorporation into finished products; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(*1*) The label clearly states that the product is for use only by physicians or veterinarians;

(*2*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(*3*) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(1) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(2) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(3) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) *Contents of Directions for Use.* The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning (See Table in § 162.10(h)(1)(iv)).

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) *Statement of Use Classification.* By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j) (1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) *General Use Classification.* Pesticide products bearing directions for

use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) *Restricted Use Classification.* Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) *Front panel statement of restricted use classification.* (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 36571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978]

TABLE D

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED (Refer to the sample labels following)

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT OF LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product Name	All Products	Front panel	Center front panel	
2	Company Name and Address	All Products	None	Bottom front panel or end of label test	If registrant is not the producer must be qualified by "Packed For," "Distributed by," etc.
3	Net Contents	All Products	None	Bottom front panel or end of label test	May may in metric units in addition to U.S. units.
4	EPA Est. No.	All Products	None	Front Panel	Must be in similar type size and run parallel to other type.
5	EPA Reg. No.	All Products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients Statements	All Products	Front Panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/Gallon Statement	Liquid products where dosage given as lbs ai/unit area	Front Panel	Directly below the main ingredients statement	
7	Front Panel Precautionary Statements	All Products	Front Panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child Hazard Warning)	All Products	Front Panel	Above signal word	Note type size requirements.

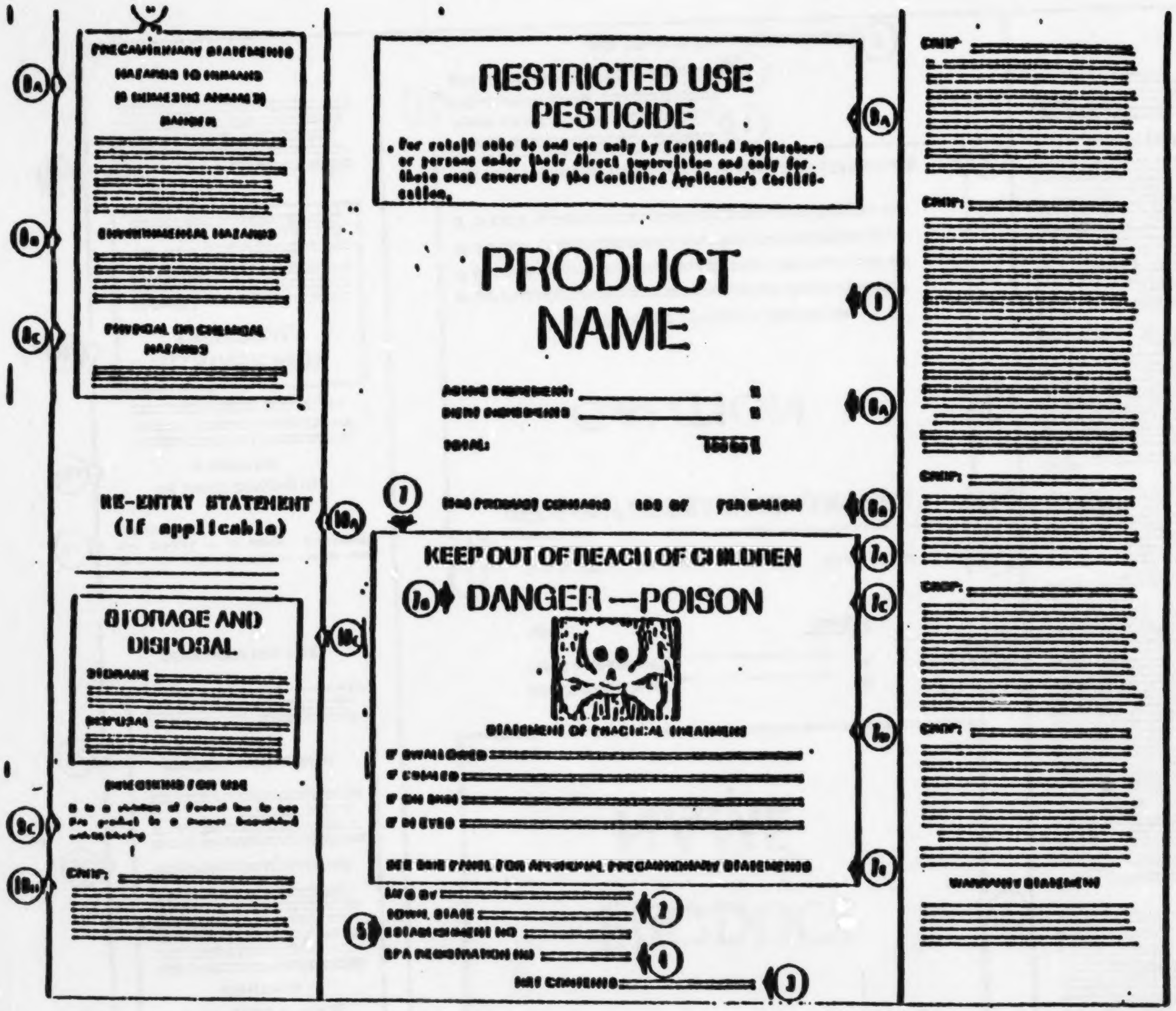
TABLE E

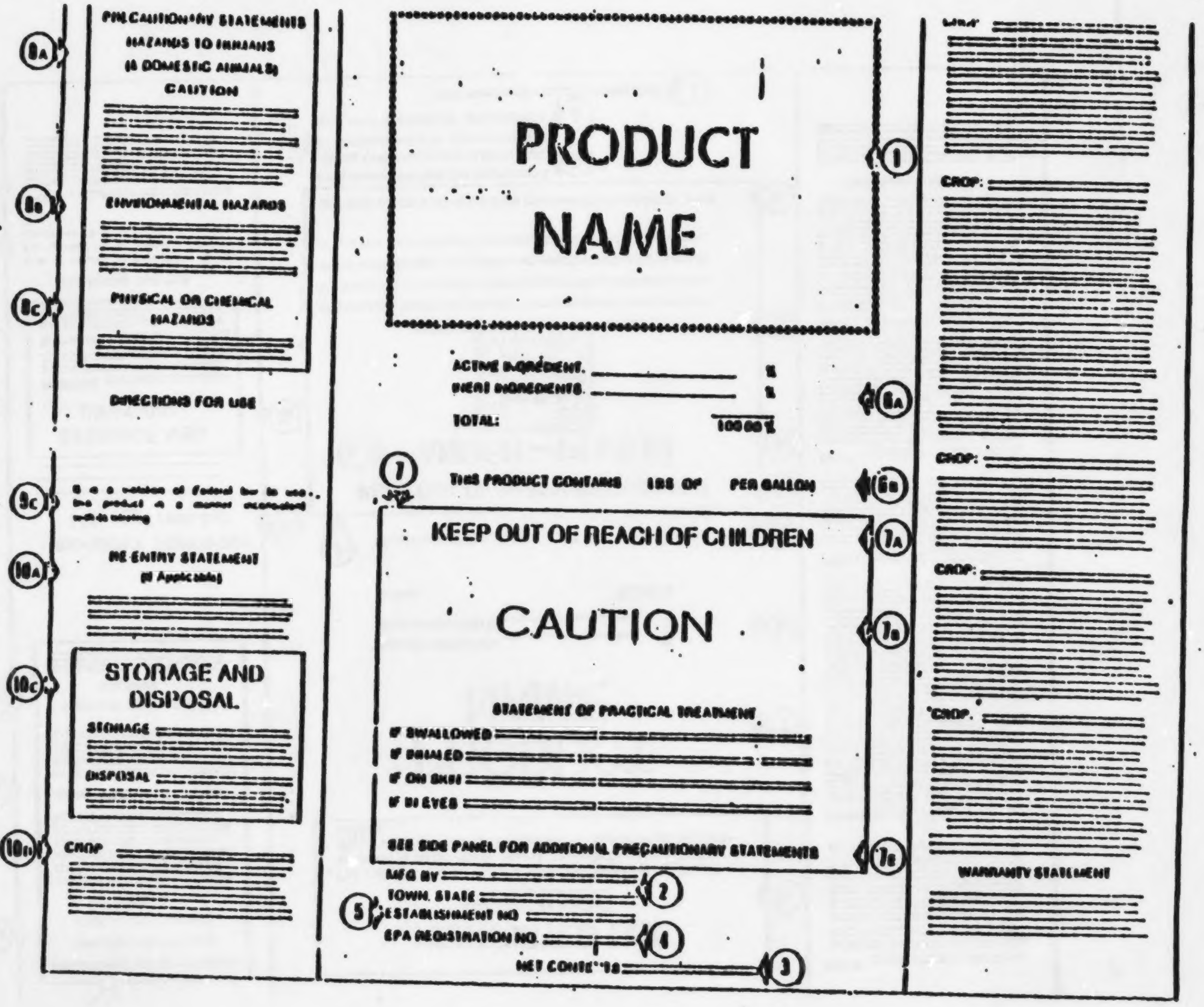
LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED (Refer to the sample labels following)

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT OF LABEL		COMMENTS
			REQUIRED	PREFERRED	
7B	Signal Word	All Products	Front panel	Immediately below Child Hazard Warning	Note type size requirements
7C	Skull & Cross-bones add word "POISON" (In red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front Panel	Both in close proximity to signal word	
7D	Statement of Practical Treatment	All products in Categories I, II, and III	Category 1: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements	Front panel for all	
7E	Referral Statement	All products where precautionary labeling appears on other than front panel	Front panel		
8	SIDE/BACK PANEL PRECAUTIONARY STATEMENTS	All Products	None	Top or side of back panel preceding Directions for Use	Must be grouped under the headings in 8a, 8b, and 8c, preferably blocked.
8A	Hazards to Humans and Domestic Animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental Hazards	All Products	None	Same as above	Environmental hazards include use caution where applicable.
8C	Physical or Chemical Hazards	All pressurized products, others with flashpoints under 150 °F	None	Same as above	

TABLE F

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT OF LABEL		COMMENTS
			REQUIRED	PREFERRED	
9A	Restricted Block	ALL RESTRICTED Products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words, "RESTRICTED USE PESTICIDE" must be same size as signal word.
9C	Misuse Statement	All Products	Immediately following Statement of Classification or head of Directions for Use		
10A	Reentry Statement	All cholinesterase inhibitors	In the Directions for Use	Immediately after Misuse Statement	
10C	Storage and Disposal Block	All Products	In the Directions	Immediately before specific directions for use or at the end of directions for use	Must be grouped together, and preferably blocked. Heading must be same type as Child Hazard Warning.
10D U.S.	Directions for Use	All Products	None	None	May be in metric units as well as U.S. units.


PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS
(& DOMESTIC ANIMALS)
DANGER
ENVIRONMENTAL HAZARDS
PHYSICAL OR CHEMICAL HAZARDS
RE-ENTRY STATEMENT
(If applicable)
STORAGE AND DISPOSAL
STORAGE
DISPOSAL
DIRECTIONS FOR USE
It is a violation of Federal law to use this product in a manner inconsistent with its labeling.
CROP:
RESTRICTED USE PESTICIDE
For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification.
PRODUCT NAME
ACTIVE INGREDIENT:
INERT INGREDIENTS:
TOTAL:
100.00%
THIS PRODUCT CONTAINS LBS OF PER GALLON
KEEP OUT OF REACH OF CHILDREN
DANGER—POISON
STATEMENT OF PRACTICAL TREATMENT
IF SWALLOWED
IF INHALED
IF ON SKIN
IF IN EYES
SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS
MFG BY
TOWN, STATE
ESTABLISHMENT NO
EPA REGISTRATION NO
NET CONTENTS
WARRANTY STATEMENT
1
2
3
4
5


8A
PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS
(& DOMESTIC ANIMALS)
CAUTION
8B
ENVIRONMENTAL HAZARDS
8C
PHYSICAL OR CHEMICAL
HAZARDS
DIRECTIONS FOR USE
9C
It is a violation of Federal law to use this product in a manner inconsistent with its labeling
10A
RE-ENTRY STATEMENT
(If Applicable)
10C
STORAGE AND
DISPOSAL
STORAGE
DISPOSAL
10D
CROP
1
PRODUCT
NAME
ACTIVE INGREDIENT. %
INERT INGREDIENTS. %
TOTAL: 100.00%
6A
7
THIS PRODUCT CONTAINS LBS OF PER GALLON
6B
KEEP OUT OF REACH OF CHILDREN
7A
CAUTION
7B
STATEMENT OF PRACTICAL TREATMENT
IF SWALLOWED
IF INHALED
IF ON SKIN
IF IN EYES
SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS
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MFG BY
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ESTABLISHMENT NO.
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CROP:
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CROP:
WARRANTY STATEMENT

Appendix V-3

Physical - Chemical Hazards

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoints at or below 20 °F; or if there is a flashback at any valve opening	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130 °F may cause bursting.
B. Flashpoint above 20 °F and not over 80 °F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130 °F may cause bursting.
C. ALL OTHER PRESSURIZED CONTAINERS	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130 °F may cause bursting.
II. Nonpressurized Containers	
A. Flashpoint at or below 20 °F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20 °F and over 80 °F	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80 °F	Do not use or store near heat and open flame.
D. Above 150 °F	None required.

APPENDIX V-4

162.11

(c) *Use classification*—(1) *Classification criteria for new registrations.* Except as provided in paragraph (c)(4) of this section, a specific use(s) of a pesticide product not previously registered shall be classified for general use if each of the applicable criteria set forth in paragraph (c)(1)(i)–(iii) of this section is met. Otherwise, the product use(s) shall be classified for restricted use unless a review of the labeling pursuant to paragraph (c)(3) of this section indicates that the product use may be classified for general use or the benefits from unrestricted use of the pesticide outweigh the risks of unrestricted use of the pesticide. Each of the separate criteria as set forth below must be applied for the product use(s) to be classified unless the formulation, packaging, or method of use of the product can reasonably be expected to eliminate the route of exposure. New data submitted to support classification must conform to the specifications of the Registration Guidelines.

(i) *Domestic applications.* A pesticide use(s) intended for domestic application will be a candidate for general use classification if the pesticide formulation:

(A) Has an acute dermal LD_{50} greater than 2,000 mg/kg;

(B) Has an inhalation LC_{50} greater than 2 mg/liter;

(C) Causes no corneal opacity, or causes eye irritation reversible within 7 days or less;

(D) Causes no more than moderate skin irritation within 72 hours;

(E) Has an acute oral LD_{50} greater than 1.5 g/kg for the formulation as diluted for use; and

(F) Causes, under conditions of label use or widespread and commonly recognized practice of use, only minor or no discernible subacute, chronic, or delayed effects on man or other nontarget organisms from single or multiple exposures to the product ingredient(s), their metabolite(s), or degradation product(s).

(ii) *Nondomestic applications.* A pesticide use(s) intended for nondomestic application will be a candidate for general use classification if the pesticide formulation:

(A) Has an acute dermal LD_{50} greater than 200 mg/kg;

(B) Has an acute dermal LD_{50} greater than 16 g/kg for the formulation as diluted for use as a mist or spray;

(C) Has an inhalation LD_{50} greater than 0.2 mg/liter;

(D) Is not corrosive to the eye or causes corneal opacity reversible within 7 days;

(E) Is not corrosive to the skin and causes no more than severe skin irritation within 72 hours; and

(F) Causes under conditions of label use, or widespread and commonly recognized practice of use, only minor or no discernible subacute, chronic, or delayed toxic effects on man or other nontarget organisms from single or multiple exposures to the product ingredient(s), their their metabolite(s), or degradation product(s).

(iii) *Outdoor applications.* A pesticide use(s) intended for outdoor application will be a candidate for general use classification if it meets the applicable set of criteria set forth immediately above for either domestic or nondomestic application, as appropriate, and if the pesticide:

(A) Occurs as a residue immediately following application in or on the feed of a mammalian species representative of the species likely to be exposed to such feed in amounts equivalent to the average daily intake of such representative species, at levels less than ⅕ the acute oral LD_{50} measured in mammalian test animals as specified in the Registration Guidelines.

(B) Occurs as a residue immediately following application in or on the feed of an avian species representative of the species likely to be exposed to such feed in amounts equivalent to the average daily intake of such representative species, at levels less than ⅕ the subacute dietary LC_{50} measured in avian test animals as specified in the Registration Guidelines.

(C) Results in a maximum calculated concentration following direct application to a 6-inch layer of water less than ⅒ the acute LC_{50} for aquatic organisms representative of the organisms likely to be exposed as measured in test animals as specified in the Registration Guidelines.

(D) The pesticide causes, under conditions of label use, or widespread and commonly recognized practice of use, only minor or no discernible adverse effects on the physiology, growth, population levels, or reproduction rates of nontarget organisms, resulting from exposure to the product ingredients, their metabolites, or degradation products, whether due to direct application or otherwise resulting from application, such as through volatilization, drift, leaching or lateral movement in soil.

(2) *Classification criteria for previously registered products.* All pesticide products registered by this Agency prior to October 21, 1974 have been assigned a Toxicity Category [see § 162.10(h)(1)]. Unless the applicant for reregistration submits or has submitted the toxicity data on the product use(s) required in paragraph (c)(1) of this section, the existing Toxicity Category determinations shall be used to establish whether the pesticide use(s) is a candidate for general or restricted use classification. Except as provided in paragraph (c)(4) of this section, specific use(s) of a product shall be classified for general use if the applicable criteria set forth in paragraph (c)(2) (i)–(iii) of this section are met. Otherwise, the product use shall be classified for restricted use unless a review of the labeling pursuant to paragraph (3) of this paragraph (c) indicates that the use may be classified for general use or the benefits from unrestricted use of the pesticide outweigh the risks of unrestricted use of the pesticide. Each of the separate criteria as set forth below must be applied for the product use(s) to be classified unless the formulation, packaging, or method of use of the product can reasonably be expected to eliminate the route of exposure.

(i) *Domestic applications.* A pesticide use(s) intended for domestic application shall be a candidate for general use classification if the pesticide formulation:

(A) Does not meet the criteria of Toxicity Category I or II; and

(B) Causes, under conditions of label use, or widespread and commonly recognized practice of use, minor or no discernible subacute, chronic, or delayed effects on man or other nontarget organisms from single or multiple exposures to the product ingredients, their metabolites, or degradation products.

(ii) *Nondomestic applications.* A pesticide use(s) intended for nondomestic application shall be a candidate for general use classification if the pesticide formulation:

(A) Does not meet the criteria of Toxicity Category I; and

(B) Causes, under conditions of label use, or widespread and commonly recognized practice of use, only minor or no discernible subacute, chronic, or delayed toxic effects on man or other nontarget organisms from single or multiple exposures to the product ingredients, their metabolites, or degradation products.

(iii) *Outdoor applications.* A pesticide use(s) intended for outdoor application will be a candidate for general use classification if it meets the applicable set of criteria set forth immediately above for either domestic or nondomestic application as appropriate, and if the pesticide:

(A) Occurs as a residue immediately following application in or on the feed of a mammalian species representative of the species likely to be exposed to such feed in amounts equivalent to the average daily intake of such representative species, at levels less than ⅕ the acute oral LD_{50} measured in mammalian test animals as specified in the Registration Guidelines.

(B) Occurs as a residue immediately following application in or on the feed of an avian species representative of the species likely to be exposed to such feed in amounts equivalent to the average daily intake of such representative species at levels less than ⅕ the subacute dietary LC_{50} measured in avian test animals as specified in the Registration Guidelines.

(C) Results in a maximum calculated concentration following direct application to a 6-inch layer of water less than $\frac{1}{10}$ the acute LC_{50} for aquatic organisms representative of the organisms likely to be exposed as measured in test animals as specified in the Registration Guidelines.

(D) The pesticide causes, under conditions of label use, or widespread and commonly recognized practice of use, only minor or no discernible adverse effects on the physiology, growth, population levels, or reproduction rates of nontarget organisms, resulting from exposure to the product ingredients, their metabolites, or degradation products, whether due to direct application or otherwise resulting from the application, such as through volatilization, drift, leaching or lateral movement in soil.

(3) *Adequacy of label and labeling.* The directions, warnings, and cautions for any product use(s) not meeting the criteria set forth in paragraphs (c) (1) and (2) of this section shall be further evaluated according to the criteria set forth below to determine the adequacy of the label or labeling to prevent unreasonable adverse effects on man or the environment. If these criteria are met, the labeling for the affected uses will be considered adequate to prevent unreasonable adverse effects on the environment without further regulatory restrictions, and the affected uses will be classified for general use. The criteria for evaluating labeling adequacy are as follows:

(i) To follow label directions, the user of a pesticide product would not have to perform complex operations or procedures requiring specialized training and/or experience;

(ii) Failure to follow the use directions in any minor way would result in minor or no discernible adverse effects;

(iii) Widespread and commonly recognized practices of use would not nullify label directions relative to prevention of unreasonable adverse effects on man and the environment;

(iv) The directions do not call for specialized apparatus, protective equipment or material unless they would be expected to be available to the general public;

(v) Following directions for use would result in only minor or no discernible adverse effects of a delayed or indirect nature, such as through bioaccumulation, persistence, or pesticide movement from the original application site, on nontarget organisms.

(4) *Other Hazards.* Any product use(s) which meets the general use criteria of paragraph (c) (1), (2), or (3) of this section shall nonetheless be classified for restricted use if the Agency determines that based on human toxicological data (including epidemiological studies), use history, accident data, monitoring data, or such other evidence as the Administrator identifies the product use(s) may pose a serious hazard to man or the environment which can reasonably be prevented by classification for restricted use.

(5) *Other regulatory restrictions.* Any product use(s) classified for restricted use under the provisions above may be limited to use by or under the direct supervision of a certified applicator. The Administrator may additionally or alternatively impose other restrictions by regulation. Such regulatory restrictions may include, but are not limited to, seasonal or regional limitations, limitation of use to approved pest management programs, or a requirement for monitoring of residue levels after use, and may be utilized to reduce human health and environmental hazards associated with persistent, bioaccumulative, or mobile, or highly toxic pesticides. Any such regulation shall be reviewable in the appropriate Court of Appeals upon petition of a person adversely affected filed within 60 days of the publication of such regulation in final form.

PROPOSED DISPOSAL STATEMENTS FOR PESTICIDES

PESTICIDE DISPOSAL (all except household)

Pesticide, spray mixture, or rinsate that cannot be used according to label instructions must be disposed of according to Federal, State, or local procedures under the Resource Conservation and Recovery Act.

CONTAINER DISPOSAL

1. Household (all)

   Do not reuse empty container (bottle, can, bucket). Wrap (container) and put in trash collection.

2. Metal (all sizes)

   Triple rinse (or equivalent) and offer for recycling or reconditioning, or dispose of in a sanitary landfill, or by other approved State and local procedures.

3. Plastic (all)

   Triple rinse (or equivalent) and offer recycling or reconditioning, or dispose of in a sanitary landfill, or by incineration if permitted by State and local authorities.

4. Glass (all)

   Triple rinse (or equivalent) and dispose of in a sanitary landfill or by other approved State and local procedures.

5. Fiber drums with liners

   Dispose of liners according to approved Federal, State, or local procedures under the Resource Conservation and Recovery Act. If container cannot be reused*, dispose of in a sanitary landfill or by incineration if permitted by State and local authorities.

*Manufacturer should replace this phrase with one indicating whether and how fiber container may be reused.

6. Paper and plastic bags

Dispose of bags according to approved Federal, State, or local procedures under the Resource Conservation and Recovery Act.

7. Compressed gas cylinders

Return empty cylinder for reuse (or similar wording).

APPENDIX V-6

§ 162.16 Pesticides requiring special packaging.

(a) *General.* This section implements Section 25(c)(3) of the Act, which authorizes the Administrator to establish standards with respect to the package, container or wrapping in which a pesticide or device is enclosed in order to protect children and adults from serious injury or illness resulting from accidental ingestion or contact with pesticides or devices regulated by this Act.

(b) *Definitions.* Terms used in this section shall have the same meaning set forth in the Act and in § 162.2. In addition, as used in this section:

(1) The term "package" means the immediate container or wrapping in which any pesticide is contained for consumption, use or storage. "Package" does not include:

(i) Any shipping container or wrapping used solely for the transportation of any pesticide in bulk or in quantity to manufacturers, packers or processors, or to wholesale or retail distributors thereof; or

(ii) Any shipping container or other wrapping used by retailers to ship or deliver any pesticide to consumers unless it is the only such container or wrapping.

(2) The term "residential application" means application of a pesticide (other than application by a commercial applicator) directly to humans or pets or application of a pesticide in, on or around all structures, vehicles or areas associated with the household or homelife or non-commercial areas where children spend time, including, but not limited to:

(i) Gardens, non-commercial greenhouses, yards, patios, houses, pleasure marine craft, mobile homes, campers and recreational vehicles, non-commercial campsites, home swimming pools and kennels;

(ii) Articles, objects, devices or surfaces handled or contacted by humans or pets in all structures, vehicles or areas listed above; and

(iii) Educational, lounging and recreational areas of preschools, nurseries and day camps.

(3) The term "special packaging" means packaging that is designed and constructed to be significantly difficult for children under five years of age to open or obtain a toxic or harmful amount of the substance contained therein within a reasonable time, and that is not difficult for normal adults to use properly.

(4) The term "unit package" means a package that is labeled with directions to use the contents in a single application or which consists of individually packaged dosage units.

(c) *Pesticides requiring special packaging*—(1) *General.* Any pesticide product that is released for shipment after insert date 2 years from date of publication shall be specially packaged if (i) its labeling allows residential use, (ii) it has not been classified for restricted use and (iii) it meets the toxicity criteria in paragraph (c)(2) of this section. Special packaging may be required on a case-by-case basis for pesticide products which are classified for restricted use, if the Administrator determines that there is a serious hazard of accidental injury or illness which special packaging could reduce.

(2) *Criteria for special packaging.* Special packaging is required for a pesticide product approved for residential application if the tests conducted in accordance with Part 162 indicate that the pesticide formulation:

(i) Has an acute dermal LD_{50} of 2000 mg/kg or less;

(ii) Has an inhalation LC_{50} of 2 mg/liter or less;

(iii) Is corrosive to the eye (causes irreversible destruction of ocular quest, for inspection and copying purposes or for submission to EPA.

(1) A full description of the package including:

(i) A full description of the container including:

(A) Its dimensions, and

(B) Its composition; and

(ii) A full description of the closure or special package, if appropriate, including:

(A) The name of its manufacturer.

(B) The manufacturer's designation (title) for the special packaging closure or the physical working of the special packaging mechanism, and

(C) The explicit directions for proper use of the closure or special packaging and the placement of these directions on the package;

(2) A complete copy of the data resulting from the tests conducted in accordance with § 162.16(d); and

(3) Data demonstrating the compatibility of the pesticide formulation with the entire package to determine that the chemical and physical characteristic of the substances will not interfere with the safety and efficacy of the pesticide and the functioning of the special package.

(g) *Enforcement.* Failure to comply with this rule by its implementation date renders a pesticide misbranded under Section 2(q)(1)(E) of FIFRA, and is a violation of Section 12(a)(1)(E) of FIFRA. Registrants who violate these sections will be subject to civil and criminal penalties under Section 14 of FIFRA.

(Secs. 3 and 25(c)(3), Federal Insecticide, Fungicide, and Rodenticide Act, as amended (Pub. L. 92-516, 86 Stat. 973; Pub. L. 94-140, 89 Stat. 751; 7 U.S.C. 136 et seq.))

[44 FR 13022, Mar. 9, 1979]

tissue) or causes corneal involvement or irritation persisting for 21 days or more;

(iv) Is corrosive to the skin (causes tissue destruction into the dermis and/or scarring) or causes severe skin irritation (severe erythema or edema) at 72 hours;

(v) Has an acute oral LD_{50} of 1.5 g/kg or less; or

(vi) Has such characteristics that, based upon human toxicological data, use history, accident data or such other evidence as is available, the Administrator determines that there is a serious hazard of accidental injury or illness which special packaging could reduce.

(3) *Exemptions.* Upon the request of a registrant or applicant the Administrator may on a case-by-case basis, grant an exemption, based on supporting data accompanying the request, for products for which special packaging is not technically feasible or for those pesticides for which the hazards indicated by the toxicity criteria in paragraph (c)(2) of this section are not indicative of hazard to man. Any such decision shall be published in the FEDERAL REGISTER and shall be applicable to any product with identical or substantially similar composition and intended uses.

(4) *Unit packaging.* Pesticides requiring special packaging and which use unit packaging shall either package each unit package in a special package or use special packaging for the retail container which contains unit packages. Special packaging will not be required for both the outer container and the unit packages unless, on a case-by-case basis, further information shows that it is necessary for hazard reduction.

(d) *Standards for special packaging*—(1) *General requirements.* (i) The special packaging must continue to function with the effectiveness specifications set forth in paragraph (d)(2) of this section when in actual use as a pesticide container. This requirement may be satisfied by appropriate scientific evaluation of the compatibility of the substance with the special packaging to determine that the chemical and physical characteristics of the substance will not compromise or interfere with the proper functioning of the special packaging and that the packaging will not be detrimental to the integrity of the product during storage and use.

(ii) The special packaging must continue to function with the effectiveness specified in paragraph (d)(2) of this section for the reasonably expected lifetime of the package, taking into account the number of times the package is customarily opened and closed. This requirement may be satisfied by appropriate technical evaluation based on physical wear and stress factors, force required for activation, and other relevant factors.

(2) *Effectiveness specifications.* The special packaging, when tested by the method referred to in paragraph (d)(3) of this section, shall meet the following specifications:

(i) Child-resistant effectiveness of not less than 85 percent without a demonstration and not less than 80 percent after a demonstration of the proper means of opening the package. In the case of unit packaging, child-resistant effectiveness of not less than 80 percent.

(ii) Adult-use effectiveness of not less than 90 percent without a demonstration.

(3) *Effectiveness testing procedures.* Standards for special packaging shall be evaluated for each size of a design used pursuant to the Consumer Product Safety Commission (CPSC) protocols specified in 16 CFR 1700.20(a), (b), (c) and (d).

(e) *Submission.* The registrant of a registered pesticide which requires special packaging shall submit an application for amended registration under § 162.6(b)(3). The application shall include a certification by the registrant that the package meets the standards of § 162.16(d). An applicant for a new registration shall submit a certification statement that the package meets the standards of § 162.16(d) with the application for registration.

(f) *Record keeping.* The applicant or registrant of a pesticide for which special packaging is required shall retain the records described in paragraphs (f)(1), (2), and (3) of this section for as long as the registration is valid. These records shall be available, upon re-

Naphthaleneacetic Acid
its Salts, Ester,
and Acetamide

Pesticide Registration Standard

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CHAPTER I: HOW TO REGISTER UNDER A REGISTRATION STANDARD

A. Organization of the Standard
B. Purpose of the Standard
C. Requirement to Re-register Under the Standard
D. "Product Specific" Data and "Generic" Data
E. Data Compensation Requirements under FIFRA 3(c)(1)(D)
F. Obtaining Data to Fill " Data Gaps"; FIFRA 3(c)(2)(B)
G. Amendments to the Standard

A. Organization of the Standard

This first chapter explains the purpose of a Registration Standard and summarizes the legal principles involved in registering or re-registering under a Standard. The second chapter sets forth the requirements that must be met to obtain or retain registration for products covered by this particular Registration Standard. In the remaining chapters, the Agency reviews the available data by scientific discipline, discusses the Agency's concerns with the identified potential hazards, and logically develops the conditions and requirements that would reduce those hazards to acceptable levels.

B. Purpose of the Standard

Section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) provides that "no person in any State may distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive (and having so received) deliver or offer to deliver, to any person any pesticide which is not registered with the Administrator [of EPA]." To approve the registration of a pesticide, the Administrator must find, pursuant to Section 3(c)(5) that:

"(A) its composition is such as to warrant the proposed claims for it;

(B) its labeling and other material required to be submitted comply with the requirements of this Act;

(C) it will perform its intended function without unreasonable adverse effects on the environment; and

(D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment."

In making these findings, the Agency reviews a wide range of data which registrants are required to submit, and assesses the risks and benefits associated with the use of the proposed pesticide. But the established approach to making these findings has been found to be defective on two counts:

First, EPA and its predecessor agency, the United States Department of Agriculture (USDA), routinely reviewed registration applications on a "product by product" basis, evaluating each product-specific application somewhat independently. In the review of products containing similar components, there was little opportunity for a retrospective review of the full range of pertinent data available in Agency files and in the public literature. Thus th "product by product" approach was often inefficient and sometimes resulted in inconsistent or incomplete regulatory judgments.

Second, over the years, as a result of inevitable and continuing advances in scientific knowledge, methodology, and policy, the data base for many pesticides came to be considered inadequate by current scientific and regulatory standards. Given the long history of pesticide regulation in several agencies, it is even likely that materials may have been lost from the data files. When EPA issued new requirements for registration in 1975 (40 CFR 162) and proposed new guidelines for hazard testing in 1978 (43 FR 29686, July 10, 1978 and 43 FR 37336, August 22, 1978), many products that had already been registered for years were being sold and used without the same assurances of human and environmental safety as was being required for new products. Because of this inconsistency, Congress directed EPA to re-register all previously registered products, so as to bring their registrations and their data bases into compliance with current requirements, [See FIFRA Section 3(g)].

Facing the enormous job of re-reviewing and calling-in new data for the approximately 35,000 current registrations, and realizing the inefficiencies of the "product by product" approach, the Agency decided that a new, more effective method of review was needed.

A new review procedure has been developed. Under it, EPA publishes documents called Registration Standards, each of which discusses a particular pesticide active ingredient. Each Registration Standard summarizes all the data available to the Agency on a particular active ingredient and its current uses, and sets forth the Agency's comprehensive position on the conditions and requirements for registration of all existing and future products which contain that active ingredient. These conditions and requirements, all of which must be met to obtain or retain full registration or reregistration under Section 3(c)(5) of FIFRA, include the submission of needed scientific data which the Agency does not now have, compliance with standards of toxicity, composition, labeling, and packaging, and satisfaction of the data compensation provisions of FIFRA Section 3(c)(1)(D).

The Standard will also serve as a tool for product classification. As part of the registration of a pesticide product, EPA may classify each product for "general use" or "restricted use" [FIFRA Section 3(d)]. A pesticide is classified for "restricted use" when some special regulatory restriction is needed to ensure against unreasonable adverse effects to man or the environment. Many such risks of unreasonable adverse effects can be lessened if expressly-designed label precautions are strictly followed. Thus the special regulatory restriction for a "restricted use" pesticide is usually a requirement that it be applied only by, or under the supervision of, an applicator who has been certified by the State or Federal government as being competent to use pesticide safely, responsibly, and in accordance with label directions. A restricted-use pesticide can have other regulatory restrictions [40 CFR 162.11(c)(5)] instead of, or in addition to, the certified applicator requirement. These other regulatory restrictions may include such actions as seasonal or regional limitations on use, or a requirement for the monitoring c residue levels after use. A pesticide classified for "general use," or not classified at all, is available for use by any individual who is in compliance with State or local regulations. The Registration Standard review compares information about potential adverse effects of specific uses of the pesticide with risk criteria listed in 40 CFR 162.11(c), and thereby determines whether a product needs to be classified for "restricted use." If the Standard does classify a pesticide for "restricted use," this determination is stated in the second chapter.

C. Requirement to Reregister Under the Standard

FIFRA Section 3(g), as amended in 1978, directs EPA to reregister all currently registered products as expeditiously as possible. Congress also agreed that reregistration should be accomplished by the use of Registration Standards.

Each registrant of a currently registered product to which this Standard applies, and who wishes to continue to sell or distribute his product in commerce, must apply for reregistration. His application must contain proposed labeling that complies with this Standard.

EPA will issue a notice of intent to cancel the registration of any currently registered product to which this Standard applies if the registrant fails to comply with the procedures for reregistration set forth in the Guidance Package which accompanies this Standard.

D. "Product Specific" Data and "Generic" Data

In the course of developing this Standard, EPA has determined the types of data needed for evaluation of the properties and effects of products to which the Standard applies, in the disciplinary areas of Product Chemistry, Environmental Fate, Toxicology, Residue Chemistry, and Ecological Effects. These determinations are based primarily on the data Guidelines proposed in 43 FR 29696, July 10, 1978; 43 FR 37336, August 22, 1978; and 45 FR 72948, November 3, 1980, as applied to the use patterns of the products to which this Standard applies. Where it appeared that data from a normally applicable Guidelines requirement was actually unnecessary to evaluate these products, the Standard indicates that the requirement has been waived. On the other hand, in some cases studies not required by the Guidelines may be needed because of the particular composition or use pattern of products the Standard covers; if so, the Standard explains the Agency's reasoning. Data guidelines have not yet been proposed for the Residue Chemistry discipline, but the requirements for such data have been in effect for some time and are, the Agency believes, relatively familiar to registrants. Data which we have found are needed to evaluate the registrability of some products covered by the Standard may not be needed for the evaluation of other products, depending upon the composition, formulation type, and intended uses of the product in question. The Standard states which data requirements apply to which product categories. (See the third chapter.) The various kinds of data normally required for registration of a pesticide product can be divided into two basic groups:

1. Data that are product specific , i.e. data that relates only to the the properties or effects of a product with a particular composition (or a group of products with closely similar composition); and

2. Generic data that pertain to the properties or effects of a particular ingredient, and thus is relevant to an evaluation of the risks and benefits of all products containing that ingredient (or all such products having a certain use pattern), regardless of any such product's unique composition.

The Agency requires certain "product specific" data for each product to characterize the product's particular composition and physical/chemical properties (Product Chemistry), and to characterize the product's acute toxicity (which is a function of its total composition). The applicant for registration or reregistration of any product, whether it is a manufacturing-use or end-use product, and without regard to its intended use pattern, must submit or cite enough of this kind of data to allow EPA to evaluate the product. For such purposes, "product specific" data on any product other than the applicant's is irrelevant, unless the other product is closely similar in composition to the applicant's. (Where it has been found practicable to group similar products for purposes of evaluating, with a single set of tests, all products in the group, the Standard so indicates.) "Product specific" data on the efficacy of particular end-use products is also required where the exact formulation may affect efficacy and where failure of efficacy could cause public health problems.

All other data needed to evaluate pesticide products concerns the properties effects of a particular ingredient of products (normally a pesticidally active ingredient, but in some cases a pesticidally inactive, or "inert", ingredient). Some data in this "generic" category are required to evaluate the properties and effects of all products containing that ingredient [e.g., the acute LD-50 of the active ingredient in its technical or purer grade; see proposed 40 CFR 163.81-1(a), 43 FR 37355].

Other "generic" data are required to evaluate all products which both contain a particular ingredient and are intended for certain uses (see, e.g., proposed 40 CFR 163.82-1, 43 FR 37363, which requires subchronic oral testing of the active ingredient with respect to certain use patterns only). Where a particular data requirement is use-pattern dependent, it will apply to each end-use product which is to be labeled for that use pattern (except where such end-use product is formulated from a registered manufacturing-use product permitting such formulations) and to each manufacturing-use product with labeling that allows it to be used to make end-use products with that use pattern. Thus, for example, a subchronic oral dosing study is needed to evaluate the safety of any manufacturing-use product that legally could be used to make an end-use, food-crop pesticide. But if an end-use product's label specified it was for use only in ways that involved no food/feed exposure and no repeated human exposure, the subchronic oral dosing study would not be required to evaluate the product's safety; and if a manufacturing-use product's label states that the product is for use only in making end-use products not involving food/feed use or repeated human exposure, that subchronic oral study would not be relevant to the evaluation of the manufacturing-use product either.

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If a registrant of a currently registered manufacturing-use or end-use product wishes to avoid the costs of data compensation [under FIFRA Section 3(c)(1)(D)] or data generation [under Section 3(c)(2)(B)] for "generic" data that is required only with respect to some use patterns, he may elect to delete those use patterns from his labeling at the time he reregisters his product. An applicant for registration of a new product under this Standard may similarly request approval for only certain use patterns.

E. Data Compensation Requirements under FIFRA 3(c)(1)(D)

Under FIFRA Section 3(c)(1)(D), an applicant for registration, reregistration, or amended registration must offer to pay compensation for certain existing data the Agency has used in developing the Registration Standard. The data for which compensation must be offered is all data which are described by all the following criteria:

1. The data were first submitted to EPA (or to its predecessor agencies, USDA or FDA), on or after January 1, 1970;
2. The data were submitted to EPA (or USDA or FDA) by some other applicant or registant in support of an application for an experimental use permit, an amendment adding a new use to a registration, or for registration, or to support or maintain in effect an existing registration;
3. They are the kind of data which are relevant to the Agency's decision to register or reregister the applicant's product under the Registration Standard, taking into account the applicant's product's composition and intended use pattern(s);
4. The Agency has found the data to be valid and usable in reaching regulatory conclusions; and
5. They are not data for which the applicant has been exempted by FIFRA Section 3(c)(2)(D) from the duty to offer to pay compensation. (This exemption applies to the "generic" data concerning the safety of an active ingredient of the applicant's product, not to "product specific" data. The exemption is available only to applicants whose product is labeled for end-uses for which the active ingredient in question is present in the applicant's product because of his use of another registered product containing that active ingredient which he purchases from another producer.)

An applicant for reregistration of an already registered product under this Standard, or for registration of a new product under this Standard, accordingly must determine which of the data used by EPA in developing the Standard must be the subject of an offer to pay compensation, and must submit with his application the appropriate statements evidencing his compliance with FIFRA Section 3(c)(1)(D).

An applicant would never be required to offer to pay for "product specific" data submitted by another firm. In many, if not in most cases, data which is specific to another firm's product will not suffice to allow EPA to evaluate the applicant's product, that is, will not be useful to the Agency in determining whether the applicant's product is registrable. There may be cases, however, where because of close similarities between the composition of two or more products, another firm's data may suffice to allow EPA to evaluate some or all of the "product specific" aspects of the applicant's product. In such a case, the applicant may choose to cite that data instead of submitting data from tests on his own product, and if he chooses that option, he would have to comply with the offer-to-pay requirements of Section 3(C)(1)(D) for that data.

Each applicant for registration or reregistration of a manufacturing-use product, and each applicant for registration or reregistration of an end-use product, who is not exempted by FIFRA Section 3(c)(2)(D), must comply with the Section 3(c)(1)(D) requirements with respect to each item of "generic" data that relates to his product's intended uses.

A detailed description of the procedures an applicant must follow in applying for reregistration (or new registration) under this Standard is found in the Guidance Package for this Standard.

F. Obtaining Data to Fill "Data Gaps"; FIFRA 3(c)(2)(B)

Some of the kinds of data EPA needs for its evaluation of the properties and effects of products to which this Standard applies have never been submitted t the Agency (or, if submitted, have been found to have deficiencies rendering them inadequate for making registrability decisions) and have not been located in the published literature search that EPA conducted as part of preparing this Standard. Such instances of missing but required data are referred to in the Standard as "data gaps".

FIFRA Section 3(c)(2)(B), added to FIFRA by the Congress in 1978, authorizes EPA to require registrants to whom a data requirement applies to generate (or otherwise produce) data to fill such "gaps" and submit those data to EPA. EPA must allow a reasonably sufficient period for this to be accomplished. If a registrant fails to take appropriate and timely steps to fill the data gaps identified by a section 3(c)(2)(B) order, his product's registration may be suspended until the data is submitted. A mechanism is provided whereby two or more registrants may agree to share in the costs of producing data for which they are both responsible.

The Standard lists, in the third chapter, the "generic" data gaps and notes the classes of products to which these data gaps pertain. The Standard also points out that to be registrable under the Standard, a product must be supported by certain required "product specific" data. In some cases, the Agency may possess sufficient "product specific" data on one currently registered product, but may lack such data on another. Only those Standards which apply to a very small number of currently registered products will attempt to state definitively the " product specific" data gaps on a "product by product" basis. (Although the Standard will in some cases note which data that EPA does possess would suffice to satisfy certain "product specific" data requirements for a category of products with closely similar composition characteristics.)

As part of the process of reregistering currently registered products, EPA will issue Section 3(c)(2)(B) directives requiring the registrants to take appropriate steps to fill all identified data gaps -- whether the data in question are "product specific" or "generic" -- in accordance with a schedule.

Persons who wish to obtain registrations for new products under this Standard will be required to submit (or cite) sufficient "product specific" data before their applications are approved. Upon registration, they will be required under Section 3(c)(2)(B) to take appropriate steps to submit data needed to fill "generic" data gaps. (We expect they will respond to this requirement by entering into cost-sharing agreements with other registrants who previously have been told they must furnish the data.) The Guidance Package for this Standard details the steps that must be taken by registrants to comply with Section 3(c)(2)(B).

G. Amendments to the Standard

Applications for registration which propose uses or formulations that are not presently covered by the Standard, or which present product compositions, product chemistry data, hazard data, toxicity levels, or labeling that do not meet the requirements of the Standard, will automatically be considered by the Agency to be requests for amendments to the Standard. In response to such applications, the Agency may request additional data to support the proposed amendment to the Standard, or may deny the application for registration on the grounds that the proposed product would cause unreasonable adverse effects to the environment. In the former case, when additional data have been satisfactorily supplied, and providing that the data do not indicate the potential for unreasonable adverse effects, the Agency will then amend the Standard to cover the new registration.

Each Registration Standard is based upon all data and information available to the Agency's reviewers on a particular date prior to the publication date. This "cut-off" date is stated at the beginning of the second chapter. Any subsequent data submissions and any approved amendments will be incorporated into the Registration Standard by means of addenda, which are available for inspection at EPA in Washington, D.C., or copies of which may be requested from the Agency. When all the present "data gaps" have been filled and the submitted data have been reviewed, the Agency will revise the Registration Standard. Thereafter, when the Agency determines that the internally maintained addenda have significantly altered the conditions for registration under the Standard, the document will be updated and re-issued.

While the Registration Standard discusses only the uses and hazards of products containing the designated active ingredient(s), the Agency is also concerned with the potential hazards of some inert ingredients and impurities.

Independent of the development of any one Standard, the Agency has initiated the evaluation of some inert pesticide ingredients. Where the Agency has identified inert ingredients of concern in a specific product to which the Standard applies, these ingredients will be pointed out in the Guidance Package.

CHAPTER II: REGULATORY POSITION AND RATIONALE

A. Introduction
B. Description and Relationship of Chemicals
C. Classification Under Minor Use
D. Regulatory Position
E. Regulatory Rationale
F. Criteria for Registration Under the Standard
G. Acceptable Ranges and Limits
H. Required Labeling
I. Tolerance Reassessment

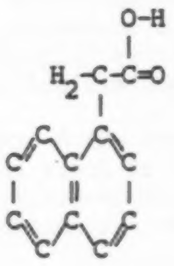
A. Introduction

This chapter presents the Agency's regulatory position and rationale based on an evaluation of all registered products containing naphthaleneacetic acid, its sodium, potassium and ammonium salts, ester and acetamide as the sole active ingredients. After briefly describing the naphthaleneacetic acid, the parent chemical of this Standard, this chapter presents the regulatory position and rationale, and the criteria for registration of products containing this chemical. These criteria include labeling considerations, and tolerance reassessment. A summary of data requirements is contained in chapter III. Data supporting this regulatory position are discussed in each of the disciplinary chapters, IV through VIII.

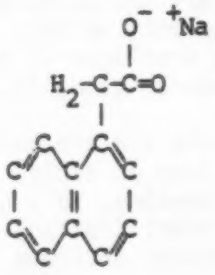
B. Description of Chemical

Naphthaleneacetic acid (NAA), its sodium and potassium salts, and its ester and acetamide are plant growth regulators which are applied as either a ground or aerial foliar spray to apples, pears, olives, quinces, pineapples and ornamentals.

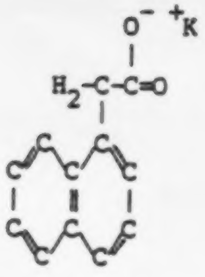
The structural formula for these chemicals are:



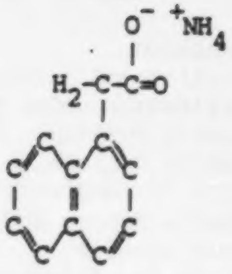
Naphthaleneacetic Acid



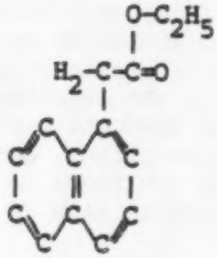
Naphthaleneacetic Acid
Sodium Salt



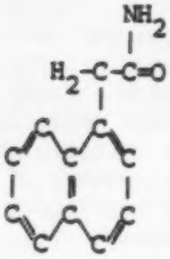
Naphthaleneacetic Acid
Potassium Salt



Naphthaleneacetic Acid
Ammonium Salt



Naphthaleneacetic Acid
Ethyl Ester



Naphthaleneacetic Acid
Acetamide

NAA, its salts, ester and acetamide are combined in this one Standard because they are structurally related and because the Agency has determined that long term toxicity testing should serve for all members of this group of chemicals.

Greenwood Chemical Company, Aceto Chemical Company and Millmaster Onyx Corporation are the principal producers of the manufacturing-use products which are available only as NAA, its sodium salt and its acetamide. Formulated products are available as dusts, soluble concentrates (liquid and solid), wettable powders, granules, pressurized liquids and emulsifiable concetrates.

These chemicals are synthetic plant growth hormones which are used to reduce pre-harvest drop of fruit, to facilitate thinning of fruit trees, induce pineapple flowering, to stimulate root growth on ornamentals, delay leaf drop in holly, prevent fruiting of ornamentals, and control resprouting from pruning wounds on certain decidous trees.

C. Classification Under Minor Use

End-use products (usually those with less than 25,000 pounds of active ingredient per year) from which exposure is expected to be minimal, based on use rates and patterns, may be classified by the Agency to be minor use chemicals.

The Agency estimates (Not derived from confidential business information estmiates) that the production of NAA and all its salts, ester and acetamide, during the most recent five year period, is between 7,000 to 15,000 pounds of active ingredient in all formulated products per year.

Accordingly, these chemicals are determined to be minor use chemicals. As a result of this classification of minor use, many data requirements, particularly in the areas of Toxicology, Residue Chemistry, Environmental Fate and Ecological Effects have been waived in this Standard. Waiving these requirements is a result of a review of the use patterns and potential exposure to humans and wildlife, which indicates that exposure is likely to be minimal.

D. Regulatory Position

Based on a review of the available scientific data and other relevant information from the open literature and submitted by registrants as of June, 1981 on naphthaleneacetic acid, its salts, ester and acetamide, the Agency has made the following determinations:

1. Pesticide products containing these chemicals as active ingredients may be registered, subject to the terms and conditions specified in this Standard.

2. None of the risk criteria found in section 162.11(a) of Title 40 U.S. Code of Federal Regulations has been met or exceeded for these active ingredients.

3. No unreasonable adverse effects have been identified for these active ingredients when used in accordance with label directions and limitations.

4. The registrant must develope or agree to develope additional data, specified in chapter III, to maintain the existing registrations or to permit new registrations.

5. The existing tolerances cannot be reassessed at this time because of the limited residue data which are available. The limited residue data which are available indicate that the established tolerances will not be exceeded when use directions are followed.

E. Regulatory Rationale

Product chemistry, ecological effects, toxicology, residue chemistry and environmental fate data available to support the registration of naphthaleneacetic acid, its salts, ester and acetamide are extremely limited. Therefore, no quantitative hazard or risk estimate could be performed for these chemicals.

Exposure to these chemicals may occur through consumption of residues retained in or on fruit and during application and mixing/loading of the formulated product. Tolerances have been established for NAA on apples, pears and quinces at 1 ppm, on olives at 0.1 ppm and on pineapples (as the sodium salt) at 0.05 ppm. Tolerances have also been established for the ethyl ester of NAA at 1 ppm on apples and pears and 0.1 ppm on olives. Tolerance of 0.1 ppm have been established for naphthaleneacetamide on apples and pears. These tolerances are for NAA. Metabolites are not included in the tolerance expression.

Because residue data are insufficient to properly reassess these tolerances, the Agency has decided to request residue data in plants. While existing residue data are meager, the Agency currently has no reason to suspect that exposure to NAA, via residues on food, will cause adverse effects. After submission of the required residue data, the Agency will reexamine the current tolerances.

Spray drift during application is not expected to be a major vehicle of exposure because of the high use-dilutions of these chemicals. Mixing/loading of these chemicals, because of contact with the concentrated product, is anticipated to result in significant respiratory, dermal and ocular exposure, and is thus considered to be the major route of exposure. The use of goggles and gloves will significantly reduce exposure during mixing/loading of end-use products. Although dermal exposure to end-use products is high during application to ornamentals, the methods of application and high use-dilutions preclude significant exposure.

While data to assess the environmental fate of NAA do not meet the current requirements, the Agency has determined that further environmental fate testing is not required at this time because of the low application rates and minor use status of these chemicals.

The Agency has not reviewed efficacy data for these chemicals because their use does not affect the public health.

Although some data gaps remain, the Agency has concluded that it should continue the registration for this chemical for the following reasons:

1. No adverse effects data of regulatory concern have been uncovered in the review of the available studies which have been received, either in studies sufficient to meet data requirements or in those which fail to meet data requirements but which provide some basis for a qualitative judgement.

2. No significant effects have been reported in the limited accident data for these chemicals.

3. In accordance with FIFRA, the Agency's policy is not to routinely cancel the registration of products merely because we lack data, or to withhold registration merely for the lack of data. (See sections 3(c)(2)(B) and 3(c)(7) of FIFRA.) Rather, publication of the Standard provides a mechanism for identifying data needs, and registration under the Standard allows for upgrading of labels during the period in which the required data are being generated. When these data are received, they will be reviewed by the Agency. The Agency will then determine whether these data will affect the registration of this chemical.

F. Criteria for Registration Under the Standard

To be subject to this Standard, products must meet the following conditions:

- contain naphthaleneacetic acid, its salts, ester or acetamide; as single active ingredients and
- bear required labeling; and
- conform to the acute toxicity limits, product composition and use pattern requirements stated in section G below.

The applicant for registration or reregistration of products subject to this Standard must comply with all terms and conditions described in this Standard including a commitment to fill data gaps on a time schedule specified by the Agency and, when applicable, offering to pay compensation to the extent required by 3(c)(1)(D) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, 7 U.S.C. 136(c)(1)(D). As discussed in Chapter I, applicants for registration under this Standard must contact the Registration Division for specific instructions, including updated information contained in the guidance package on data requirements and companies whose data must be cited and to whom compensation must be offered.

G. Acceptable Ranges and Limits

1. Manufacturing-Use Products

a. Product Composition Standard

Currently the Agency has no information on acceptable ranges and limits for the product composition of manufacturing-use products containing these chemicals. To be covered under this Standard, manufacturing-use products containing these chemicals must propose acceptable ranges and limits for both active and inert ingredients.

b. Acute Toxicity Limits

The Agency will consider registration of manufacturing-use products containing these chemicals regardless of the toxicity category, provided that they bear appropriate precautionary labeling.

c. Use Patterns and Application Methods

To be registered under this standard, manufacturing-use products containing these chemicals must be labeled to allow for formulation only into end-use products which are intended for use as:

1) synthetic plant growth hormones for use on apples, pears, olives for thinning of fruit, and/or apples and pears to prevent preharvest drop of fruit, and/or pinapples to induce flowering.

2) synthetic plant growth hormones for use on ornamentals to stimulate root growth, to delay leaf drop in holly, to prevent fruiting of ornamental olive, catalpa, elm, horsechestnut and maple trees, and to control resprouting from pruning wounds on certain deciduous trees.

2. End-Use Products

a. Product Composition Standard

Currently the Agency has no information on acceptable ranges and limits for the product composition of end-use products containing NAA, its salts ester and acetamide. To be covered under this Standard, end-use products containing these chemicals must propose acceptable ranges and limits for both active and inert ingredients.

b. Acute Toxicity Limits

The Agency will consider registration of end-use products containing these chemicals under a general-use classification, regardless of their toxicity category, provided that they bear appropriate precautionary labeling.

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c. Use Patterns and Application Methods

Currently, end-use products containing these chemicals are labeled as plant growth regulators for one or more of the uses specified in table 1.

TABLE 1

Use Sites for NAA, its Salts, Ester and Acetamide

PRODUCT TYPE	USE SITE	ACTIVE INGREDIENT
DUSTS	Apples	NAA only
	Ornamentals	Acetamide only
WETTABLE POWDERS	Apples & Pears	NAA, Sodium Salt, Acetamide
	Ornamentals	Sodium Salt only
EMULSIFIABLE CONCENTRATES	Apples & Pears	NAA only
SOLUBLE CONCENTRATES/ LIQUIDS	Apples	NAA, Ammonium & Potassium Salts, Acetamide
	Pears	NAA, Ammonium & Potassium Salts
	Olives	Potassium Salt only
	Ornamentals	NAA, Potassium & Ammonium Salts
SOLUBLE CONCENTRATES/ SOLIDS	Apples & Pears	Sodium Salt only
CRYSTALLINE	Pineapples	Sodium Salt only
READY-TO-USE PRESSURIZED LIQUIDS	Ornamentals	Ester only

Under this Standard, end-use products containing any of the chemicals covered in this Standard may be registered for any of the sites listed in table 1, provided that those uses are appropriately covered by existing tolerances.

H. Required Labeling

All manufacturing-use and end-use products containing these chemicals must bear labeling as specified in 40 CFR 162.10. The guidance package for this Standard contains specific information regarding label requirements. In addition, the following specific labeling is required:

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1. Manufacturing-Use Products

All manufacturing-use products containing these chemicals must bear one or both of the following statements on the label:

"For reformulation into products intended as growth regulators of ornamentals."

"For reformulation into products intended as growth regulators for apples, quinces, pears, pineapples, and/or olives."

These statements are necessary to identify the applicability of those data requirements which are used to support manufacturing-use products intended for use on food crops.

2. End-Use Products

Except for those end-use products containing methanol or the ethyl ester, there are no unique precautionary statements which must appear on labeling of all presently registered end-use products containing the chemicals covered in this Standard.

a. Methanol

All end-use products containing methanol must bear the following statement:

"Contains methanol"

All end-use products which contain greater than 4 percent methanol must bear the following additional statement:

"DANGER (skull & crossbones) POISON"

"Methanol may cause blindness. Harmfull or fatal if swallowed. Vapor harmful. Avoid breathing spray, mist or vapors. Avoid contact with skin."

b. Ethyl Ester

Based on data available on currently registered products, soluble concentrate end-use products which presently contain 15.1% of the ethyl ester of NAA must bear labeling indicating that the product is corrosive to the eyes and irritating to the skin. Products presently containing this chemical must bear label recommendations for the use of goggles (or face shield) and gloves.

Refer to the guidance package for an updated list of all precautionary statements which must appear on these types of products. The Agency may, after review of the data to be submitted under this Standard, impose additional label requirements.

I. Tolerance Reassessment

Tolerances have been established for NAA on apples, pears, and quinces at 1 ppm; on olives at 0.1 ppm; and in or on pineapples at 0.05 ppm (as the sodium salt). Tolerances have also been established for the ethyl ester on apples and pears at 1 ppm and on olives at 0.1 ppm. Tolerances of 0.1 ppm for the acetamide of NAA have been established on apples and pears. No CODEX tolerances exist for these chemicals.

Based on established tolerances, the theoretical human exposure to residues is calculated to be 0.0425 mg/dy/1.5 kg of diet. This figure is based on the average adult eating patterns and on the assumption that the foods contain residues which meet the established tolerance levels.

Currently a tolerance of 1 ppm exists for NAA and its ethyl ester. The limited amount of residue data currently available in addition to theoretical estimates of residues, indicate that residues of these chemicals are significantly lower than the present 1 ppm tolerance. The Agency has determined that some additional residue data are required to confirm the previously measured residues. If the requested data detect residues which are higher than those previously measured additional toxicological data may be required to support the present uses. Any future requests for new uses and/or tolerances may result in the requirement for additional toxicological, environmental fate, ecological effects and residue chemistry data.

CHAPTER III: SUMMARY OF DATA REQUIREMENTS AND DATA GAPS

A. Introduction
B. Group A Charts: Generic Data Requirements
C. Group B Charts: Manufacturing-Use Data Requirements
D. Group C Charts: End-Use Product-Specific Data Requirements

A. Introduction

Applicants for registration of end-use naphthaleneacetic acid, its salts, ester and acetamide products must cite or submit the following information on the physical/chemical properties, composition, fate, residue chemistry, ecological effects and toxicity of the proposed product. Data in this Standard that satisfy registration requirements may be cited, if the applicant establishes that the proposed product is substantially similar to another product for which the Agency has received acceptable acute toxicity tests. Data may be cited provided compensation has been offered to the submitters of these studies. The Agency will consider both active and inert ingredients in the determination of substantially similar products. (See Chapter I for discussion of substantially similar products).

The section of the Proposed Guidelines which describes the type of data and when it is required is listed before each requirement listed [43 FR, 29696 of July 10, 1978; and 43 FR, 37336 of August 22, 1978]. Justification for the required tests is provided in the Guidelines. Areas where this Standard differs from the Guidelines are discussed in the Regulatory Rationale section of Chapter II. Applicants for the reregistration of manufacturing-use or end-use products containing naphthaleneacetic acid, its salts, ester and acetamide must submit all information identified as data gaps for manufacturing-use and end-use products, respectively (see charts). The footnotes to the charts offer an explanation of additional data requirements or data waivers outside of the guidelines. The data requirements specified are the minimum that will be required. Areas where additional data may be required as the result of tiered testing are indicated.

DATA REQUIREMENTS CHART A

Naphthaleneacetic Acid, its Salts, Ester & Acetamide

Generic Data Requirements: TOXICOLOGY

Guidelines Citation	Name of Test	Are Data Required?	Composition	Does EPA have data to partially or totally satisfy this requirement?	Bibliographic Citation	Must additional data be submitted under FIFRA 3(c)(2)(B)? If so, due when?
A. Naphthaleneacetic Acid						
163.81-1	Acute Oral Toxicity	yes	Technical Grade of Active Ingredient	no	-	yes/6 months
163.81-2	Acute Dermal Toxicity	yes	Tech. Grade of A.I.	no	-	yes/6 months
163.81-3	Acute Inhalation Toxicity	yes	Tech. Grade of A.I.	no	-	yes/6 months
163.81-4	Primary Eye Irritation	yes	Tech. Grade of A.I.	no	-	yes/6 months
163.81-5	Primary Skin Irritation	yes	Tech. Grade of A.I.	no	-	yes/6 months
163.81-6	Dermal Sensitization	yes	Tech. Grade of A.I.	no	-	yes/6 months
163.82-1	Subchronic Oral Toxicity	yes	Tech. Grade of A.I.	yes	GS0023002,GS0023001 005008106,GS0023031	no
163.83-1	Chronic Feeding	yes	Tech. Grade of A.I.	no	-	no 1/
163.83-2	Oncogenicity	yes	Tech. Grade of A.I.	no	-	no 1/
163.83-3	Teratogenicity	yes	Tech. Grade of A.I.	partial	GS0023044	yes/18 Months
163.83-4	Reproduction	yes	Tech. Grade of A.I.	no	-	no 1/
163.84-2 through -4	Mutagenicity	yes	Tech. Grade of A.I.	yes	005008826,GS0023037, GS0023038,GS0023039, GS0023040,GS0023041, GS0023042,GS0023043,	no
163.85-1	Metabolism (Identification of Metabolites)	yes	Radiolabeled Analytically Pure Grade of Active Ingredient	yes	000004942,005008052	no
B. Naphthaleneacetic Acid, Ammonium Salt						
163.81	Acute Toxicity Testing	2/				
163.81-4	Primary Eye Irritation	yes	Tech. Grade of A.I.	no		yes/6 months

In addition to the above data that will be provided for the fulfillment of the requirements for the ammonium salt, the data on NAA will be considered for manufacturing use products containing the ammonium salt.

C. Naphthaleneacetic Acid, Sodium & Potassium Salts

The data for NAA will be considered for manufacturing use products containing the sodium and potassium salts.

D. Naphthaleneacetic Acid, Ethyl Ester

163.81-1	Acute Oral Toxicity	yes	Technical Grade of Active Ingredient	yes	GS0023048	no
163.81-2	Acute Dermal Toxicity	yes	Tech. Grade of A.I.	yes	GS0023047	no
163.81-3	Acute Inhalation Toxicity	yes	Tech. Grade of A.I.	yes	GS0023046	no
163.81-4	Primary Eye Irritation	yes	Tech. Grade of A.I.	yes	GS0023045	no

In addition to the above data that will be provided for the fulfillment of the requirements for the ethyl ester, the data on NAA will be considered for manufacturing use products containing the ethyl ester.

E. Naphthaleneacetamide

The data for NAA will be considered for manufacturing use products containing the acetamide of NAA.

These data requirements are current as of June, 1981. Refer to the guidance package for updated requirements.

1.Studies currently available, although inadequate by current standards, do not indicate major concerns in these areas. No further testing required at this time.

2.The requirement for this test will be determined once acute toxicity data are available for NAA.

July, 1981

DATA REQUIREMENTS CHART A

Naphthaleneacetic Acid, its Salts, Ester & Acetamide

Generic Data Requirements: RESIDUE CHEMISTRY

Guidelines Citation	Name of Test	Are Data Required?	Composition	Does EPA have data to partially or totally satisfy this requirement?	Bibliographic Citation	Must additional data be submitted under FIFRA 3(c)(2)(B)? If so, due when?
-	Metabolism in Plants	yes	Representative Formulations	yes	000004943,005009196	no 2/
-	Metabolism in Animals	yes	Representative Formulations	yes	005007964,005008070, 000004942,005008052, 005008057	no 2/
-	Analytical Methods	yes	Representative Formulations	yes	000004943,000004916, 005007967,005020083, 000004946,005002768, 005008121,005009068, GS0023012,GS0023019, GS0023036	no
-	Residue Data: Crops- Apples Pears Pineapples Olives	yes	Representative Formulations	partial	000004943,GS0023012 GS0023019,GS0023036	yes/18 months 1/ 2/
-	Dissociation Data	yes	Each A. I.	no	-	yes/12 months 2/ 3/

These data requirements are current as of June, 1981. Refer to the guidance package for updated requirements.

1.Degradation data indicate that residues in plants of ester, salts and acetamide of NAA degrade rapidly to residues of NAA and that these residues are of the same order of magnitude as those for NAA. - Additional data are required to confirm the degradation of these chemicals.

2.This data is for the technical chemicals intended for use on food crops only.

3.Data on the dissociation or hydrolysation of these chemicals must be submitted.

July, 198

DATA REQUIREMENTS CHART A

Naphthaleneacetic Acid, its Salts, Ester & Acetamide

Generic Data Requirements: ECOLOGICAL EFFECTS

Guidelines Citation	Name of Test	Are Data Required?	Composition	Does EPA have data to partially or totally satisfy this requirement?	Bibliographic Citation	Must additional data be submitted under FIFRA 3(c)(2)(B)? If so, due when?
163.71-1	Avian Single-Dose Oral LD_{50}	yes	Tech. Grade of NAA	yes	GS0023023,GS0023024	no
163.71-2	Avian Dietary LC_{50}	yes	Tech. Grade of NAA	yes	GS0023025,GS0023026	no
163.72-1	Fish Acute LC_{50}	yes	Tech. Grade of NAA	partial	GS0023022,GS0023051	yes/6 months
163.72-2	Acute Toxicity to Aquatic Invertebrates	yes	Tech. Grade of NAA	partial	GS0023050	yes/6 months
163.122-1	Seed Germination	yes	Tech. Grade of NAA	yes	005010399,005012526	no
163.122-1	Vegetative Vigor	yes	Tech. Grade of NAA	yes	005007254,005007255	no
163.122-1	Effects on Terrestrial Macrophytes	yes	Tech. Grade of NAA	no	-	yes/6 months
163.122-2	Effects on Aquatic Macrophytes	yes	Tech. Grade of NAA	no	-	yes/6 months
63.122-2	Effects on Algae	yes	Tech. Grade of NAA	no	-	yes/6 months

These data requirements are current as of June, 1981. Refer to the guidance package for updated requirements.

July, 1981

DATA REQUIREMENTS CHART B

Naphthaleneacetic Acid, its Salts, Ester & Acetamide

Manufacturing-Use Data Requirements: PRODUCT CHEMISTRY

Guidelines Citation	Name of Test	Are Data Required?	Composition	Does EPA have data to partially or totally satisfy this requirement?	Bibliographic Citation	Must additional da be submitted under FIFRA 3(c)(2)(B)? If so, due when?
163.61-3	Product Identity & Disclosure of Ingredients	yes	Each Product	no	-	yes/6 months 1 / 4
163.61-4	Description of Manufacturing Process	yes	Each Product	partial	-	yes/6 months 2 / 4
163.61-5	Discussion on Formulation of Unintentional Ingredients	yes	Each Product	no	-	yes/6 months 4 /
163.61-6	Declaration & Certification of Ingredients Limits	yes	Each Product	no	-	yes/6 months 3 / 4
163.61-7	Product Analytical Methods & Data	yes	Each Product	no	-	yes/6 months
163.64	Physical & Chemical Properties	yes	Tech. Grade of A.I. & Each Product	no	-	yes/ 4 /

These data requirements are current as of June, 1981. Refer to the guidance package for updated requirements.

1.All impurities and inerts in the technical chemicals produced by or for Greenwood Chemical Company, Millmaster Onyx Corporation and Aceto Chemical Company must be identified. Formulations of all other technical products and chemicals covered by this Standard must be identified.

2.Complete information must be supplied by each manufacturer on the present manufacturing process, including data listed in 43 FR 29709.

3.The upper and lower limits of each active and inert ingredient in manufacturing-use and end-use products must be declared and certified. The upper limit for each impurity, reaction product and degradation product must be provided. If not already cleared, all inert ingredients contained in products with food uses must be cleared by the registrant with the Food and Drug Administration.

4.These requirements must be fulfilled by each applicant. Data from other applicants may not be cited. Therefore, even if the requirement has been partially or completely fulfilled for some products, no references are given. Except for 163.61-7, these requirements must be fulfilled at the above dates.

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DATA REQUIREMENTS CHART C

Naphthaleneacetic Acid, its Salts, Ester & Acetamide

End-Use Product-Specific Data Requirements: PRODUCT CHEMISTRY

Guidelines Citation	Name of Test	Are Data Required?	Composition	Does EPA have data to partially or totally satisfy this requirement?	Bibliographic Citation	Must additional data be submitted under FIFRA 3(c)(2)(B)? If so, due when?
163.61-3	Product Identity & Disclosure of Ingredients	yes	Each Product	no	-	yes/6 months 3/
163.61-4	Description of Manufacturing Process	yes	Each Product	no	-	yes/6 months 1/ 3/
163.61-5	Discussion on Formulation of Unintentional Ingredients	yes	Each Product	no	-	yes/6 months 3/
163.61-6	Declaration & Certification of Ingredients Limits	yes	Each Product	no	-	yes/6 months 2/ 3/
163.61-7	Product Analytical Methods & Data	yes	Each Product	yes	-	no 4/
163.64	Physical & Chemical Properties	yes	Each Product	no	-	yes/6 months 3/

These data requirements are current as of June, 1981. Refer to the guidance package for updated requirements.

1.Complete information must be supplied by each manufacturer on the present manufacturing process, including data listed in 43 FR 29709.

2.The upper and lower limits of each active and inert ingredient in manufacturing-use and end-use products must be declared and certified. The upper limit for each impurity, reaction product and degradation product must be provided. If not already cleared, all inert ingredients contained in products with food uses must be cleared by the registrant with the Food and Drug Administration.

3.These requirements must be fulfilled by each applicant. Data from other applicants may not be cited. Therefore, even if the requirement has been partially or completely fulfilled for some products, no references are given. Except for 163.61-7, these requirements must be fulfilled at the above dates.

4.This data will not be required because of the minor use status of these chemicals.

July, 1981

DATA REQUIREMENTS CHART C

Naphthaleneacetic Acid, its Salts, Ester & Acetamide

End-Use Product-Specific Data Requirements: TOXICOLOGY

Guidelines Citation	Name of Test	Are Data Required?	Composition	Does EPA have data to partially or totally satisfy this requirement?	Bibliographic Citation	Must additional dat be submitted under FIFRA 3(c)(2)(B)? If so, due when?
SOLUBLE CONCENTRATES						
A. Naphthaleneacetic Acid						
163.81-4	Primary Eye Irritation	yes	Each Formulation or Substantially Similar Formulations Containing >50% Diacetone or Petroleum Oil	no	-	yes/6 months
B. Potassium Salt of Naphthaleneacetic Acid						
163.81-4	Primary Eye Irritation	yes	Each Formulation or Substantially Similar Formulations Containing >25% Isopropanol	no	-	yes/6 months
C. Naphthaleneacetic Acid, Ethyl Ester						
163.81-1	Acute Oral Toxicity	yes	Each Formulation or Substantially Similar Formulations	yes	GS0023031*	no
163.81-2	Acute Dermal Toxicity	yes	Each Formulation or Substantially Similar Formulations	yes	GS0023032	no
163.81-3	Acute Inhalation Toxicity	yes	Each Formulation or Substantially Similar Formulations	yes	GS0023034	no
163.81-4	Primary Eye Irritation	yes	Each Formulation or Substantially Similar Formulations	yes	GS0023033	no
D. Naphthaleneacetamide						
163.81-4	Primary Eye Irritation	yes	Each Formulation or Substantially Similar Formulations Containing >50% Isopropanol and Fertilizer	no	-	yes/6 months

These data requirements are current as of June, 1981. Refer to the guidance package for updated requirements.

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CHAPTER IV: PRODUCT CHEMISTRY

A. Product Chemistry - Manufacturing-Use Products
B. Product Chemistry - End-Use Products
C. Physical and Chemical Properties
D. Analytical Methods
E. Summary of Data Gaps

FIFRA 3(c)(2)(A) requires the Agency to establish guidelines for registering pesticides in the United States. We require registrants to provided quantitative data on all added ingredients, active and inert, which are equal to or greater than 0.1% of the product by weight.

To establish the composition of products proposed for registration, the Agency requires data and information not only on the manufacturing and formulation processes, but also a discussion on the formation of manufacturing impurities and other ingredients, intentional and unintentional. further, to assure that the composition of the product as marketed will not vary from the composition evaluated at the time of registration, applicants are required to submit a statement certifying upper and lower limits for the added ingredients, and upper limits only for some unintentional ingredients. Subject D suggests specific precision limits for ingredients based on the percentage of ingredient and the standard deviation of the analytical method.

In addition to the data on product composition, the Agency also requires data to establish the physical and chemical properties of both the pesticide active ingredient and its formulations. For example, data are needed concerning the identity and physical states of the active ingredient (e.g., melting point and boiling point data, ambient vapor pressure and solubility). Data are also required on the properties of the formulated product to establish labeling cautions (e.g., flammability, corrosivity or storage stability). The Agency uses these data to characterize each pesticide and to determine its environmental and health hazards.

A. Product Chemistry Manufacturing-Use Product

The technical grade of naphthaleneacetamide contains 98 percent of the acetamide. The other technical grades contain 98 or 98.5 percent of naphthaleneacetic acid or its sodium salt. The lack of identification of impurities constitutes a data gap which must be filled. The physical/chemical properties for technical 1-naphthaleneacetic acid and related chemicals covered by this Standard are not available. In addition, the inert ingredients in many manufacturing-use products containing these chemicals are not available and constitute data gaps.

Several related chemicals (the ammonium, potassium and sodium salts, the ethyl ester of naphthaleneacetic acid, and naphthaleneacetamide) are considered a part of this Standard. The lack of product chemistry data on these chemicals constitutes a data gap. Product chemistry data must be submitted on each individual chemical.

B. Product Chemistry - End-Use Products

There is little product chemistry data on many end-use products. The lack of product chemistry data for these pesticides constitutes a data gap. Product chemistry data must be submitted for all end-use products containing these chemicals. The ingredients of all formulations must be identified to 0.1% in accordance with the proposed guidelines. Those ingredients which have been added intentionally to a food-use formulation must also be cleared under 40 CFR 180.1001. The identification of the inert ingredients in many end-use products containing these chemicals are either not available or these ingredients have not been cleared as inert ingredients in pesticides used on food crops. Theseconstitute data gaps.

C. Physical and Chemical Properties

The physical and chemical properties can serve as a means of chemical identification or as a confirmation of the reliability of other composition data. The physical and chemical properties of technical, manufacturing-use and formulated products containing NAA, its salts, ester and acetamide are generally not available and, hence, constitute data gaps.

D. Analytical Methods

In order to ensure that products contain only those percentages of active ingredients which they properly claim to contain, it is necessary to have analytical methods to determine the concentration of active ingredients in each formulation. In addition, the commercial production of pesticide chemicals, reactions between pesticide ingredients, reactions with packaging materials, as well as degradation during the long period over which some products may be stored before use, can result in the formation of chemical impurities. Because of the potential toxicity of these impurities, the Agency may require submittal of analytical methods for their assessment, both to improve the reliability of the Agency's hazard assessment and to ensure that marketed products conform to the standards of purity agreed upon by the pesticide producer.

Analytical methods for the determination of the percentage of NAA in Fruit Fix Superconcentrate 800 (Crosby et al., MRID 000004943) and the percentage of the ethyl ester of NAA in Amchem Sprout Inhibitor A112 (Amchem Products, MRID GS-0023-012; Amchem Products, MRID GS-0023-019; Amchem Products, MRID GS-0023-036) are inadequate by present scientific standards. The Agency has determined that validation data (e.g. background values, recoveries, and method of sensitivity for the active ingredient) for all formulations and analytical methods for the identification and quantification of the active ingredients in all other formulations, normally required for these chemicals, will not be required because of the minor use status of these chemicals.

E. Summary of Data Gaps

A summary of the data gaps for product chemistry are listed in Chapter III.

CHAPTER V: ENVIRONMENTAL FATE

A. Use Profile
B. Environmental Fate Profile - Manufacturing-Use Products
C. Exposure Profile - End-Use Products
D. Summary of Data Gaps

A. Use Profile

Naphthaleneacetic acid, its salts, ester and acetamide are plant growth regulators registered to (1) prevent pre-harvest drop of apples, pears, quinces, olives, (2) thin fruit trees, (3) induce flower induction in pineapples, (4) stimulate root growth on ornamentals and (5) delay leaf drop on ornamentals. 7,000 to 15,000 pounds of active ingredient are produced per year with the major portion used on apples and pears. Pineapples and ornamentals are a small portion of the sites for these chemicals.

The abcission or lossening of uninjured fruits on a tree is a natural part of the maturation process in fruit. The formation of a callous abcission (separation) layer at the juncture of the fruit stem and the spur allows the weakly held fruit to fall at maturity. NAA reduces release of fruit from trees by slowing the formation of the abscission layer.

Because of its low solubility in water (0.042 g/100 ml), naphthaleneacetic acid is usually sold in the form of a salt, ester or acetamide. Even though these forms of NAA increase its solubility, NAA is reformulated with various inert ingredients (alcohol, acetone, etc.) to promote even dispersal in use dilutions of end-use products. These chemicals are formulated into dusts, wettable powders, emulsifiable concentrates, soluble concentrates/liquid, soluble concentrates/solids, granulars, pressurized liquids and ready-to-use liquids. The percentage of active ingredient in these formulations varies from 0.002 to 98 percent.

These chemicals may be applied by either ground and aerial application equipment at a concentration of approximately 10 ppm, but it may be necessary to vary the concentration of these chemicals to obtain good drop control of certain varieties of fruit. Application is made approximately 10 days prior to picking or at the first sign of sound, fully seeded fruit dropping from the tree. Longer periods of drop control may be obtained in apples by spraying 14 to 20 days prior to picking with a repeat application seven to ten days later.

Coverage of the entire fruit tree is essential because these chemicals are absorbed through the foliage and translocated only short distances within the tree stems to the fruit. Application of these chemicals is usually accomplished by ground rigs from air-blast sprayers. Approximately 1500 to 2000 gallons of spray solution is applied on three to five acres per hour. A maximum of 70 acres of mature fruit bearing trees can be covered in a ten hour day. The timing and rate of application is very critical because these chemicals require approximately three days to become effective and their effectiveness lasts from

10 to 14 days. Premature application will not prevent pre-harvest drop becaus their effect will dissipate before drop begins. Late application will deliver little or no benefit. To maintain effectiveness, application should be made at temperatures above 70°F and when rain will not occur for several hours.

The thinning of fruit from trees is an essential part of orchard management. The process of thinning involves the removal, by hand or chemical spraying, of immature fruit. Thinning results in larger, more uniform fruit size, reduces the size of fluctuations between harvests for biennial bearing trees, reduces limb breakage, and maintains tree vigor.

Historically, thinning was performed by removing, by hand, of immature fruit after a natural drop. Depending on the anticipated crop size, growers attempted to strive for a uniform number of fruit per tree, or per cluster on a tree.

Thinning with chemical agents, such as NAA, provides a means to partially or completely overcome the necessity of hand thinning and has now become a standard commercial practice in many fruit growing areas of the U.S.

Chemical thinning agents are usually sprayed while the fruit is still susceptable to the thinning effect, but after the leaves have reached a point in their development where injury to foliage would be least likely to occur. Because the results of thinning are highly variable, directions for use will depend on the weather, amount of bloom, pollination, rate of application, time of application and region of the country where the chemical is used.

The effectiveness of chemical thinning also depends upon the rate of absorpt by the leaves of the fruit tree. Absorption of thinning agents will vary between fruits and between varieties of a fruit as well as whether a wetting agent is used during application. Concentrations of these chemicals may be lowered by 50% the recommended rates when a wetting agent is used in the spray solutions. Finally, insufficient thinning one year does not necessarily warrent an increase in the concentration the next year.

Thinning may be performed with either high or low volume equipment. The main objective of effective spraying is calculation of proper dosage rates and application of these chemicals to each tree so that each tree is thouroughly covered. Failure to perform proper dosing and uniform coverage may result in low thinning activity. Spray concentrations of up to 20 ppm are used for thinning apples, up to 50 ppm for pears, and up to 150 ppm for thinning olives.

NAA is also used to induce flowering of pineapples at a rate of 25 grams A.I. per acre applied as a spray solution. It is applied when most of the crop is still in the vegetative stage. No more than two applications are made to the crop.

B. Environmental Fate Profile

Limited data are available to assess the environmental fate of naphthaleneacetic acid (NAA).

Aspergillus niger appears to metabolize NAA to 5-hydroxy NAA. Other possible products are the 4- and 6-hydroxy NAA isomers, as well as other phenolic or naphtholic compounds (Clifford & Woodcock, MRID 005011538). Because the metabolites identified in these studies are structurally related, hydroxylation thus appears to be a major route of degradation of NAA.

A coliform bacterium and two animal pathogens (Staphylococcus aureus and human type tubercle bacilli) are inhibited by NAA at 50 to 300 ppm, where as avian type tubercle bacilli are not inhibited by NAA at 50 ppm (Loveless et al., MRID 005005277) (Ukita et al., MRID 005010797). A yeast, Saccharomyces cerevisiae, is inhibited 13 to 58 percent by NAA at 100 to 500 ppm. In addition, large-cell mutants result from the induction of polyploidy (Doi et al., MRID 005008826). Two mutants of Neurospora crassa are inhibited 12 to 68 percent by NAA at 10 to 50 ppm, but a wild type control strain was not studied (Klein, MRID 005010966). An algae, Chlorella pyrenoidosa, is inhibited 40 to 80 percent by NAA at 46 to 372 ppm (Gramlich & Frans, MRID 005009027).

Thus, a wide range of microorganisms are inhibited by NAA at 10 to 500 ppm which are concentrations far in excess of the highest expected level in the soil (0.08 ppm). Most studies dealt with mutants, animal pathogens, or soil microorganisms and therefore are of questionable importance. While none of the studies reported the source and purity of the NAA used, these studies are sufficient to provide an indication that high concentrations of NAA will inhibit microorganisms.

In summary, although very little data are available to form a profile of the environmental fate of NAA, 5-hydroxy NAA is a suspected fungal metabolite of NAA. At very high concentrations, NAA is capable of inhibiting bacteria, fungi, and algae and also of inducing polyploid mutants. The available data suggest that currently approved NAA application rates will not have an effect on soil microorganisms.

Based on the minor use status of these chemicals and because the Agency would not normally require the above data on microorganisms, the above studies are for information only and need not be cited or submitted by applicants.

No other data exist on the environmental fate of these chemicals. Because these minor use chemicals, are applied at very low application rates (25 to 35 grams per acre), and are applied only once or twice per year, the Agency has determined that exposure to humans and wildlife is likely to be minimal. Accordingly, further environmental fate data requirements have been waived.

C. Exposure Profile

1. Introduction

1-Naphthaleneacetic acid (NAA) is registered for use on orchard crops and ornamentals as a growth regulator. Its total annual use is between 7,000 to 15,000 pounds. Thirty to fifty percent of this production is used primarily on apples and 20 to 30 percent of this production is used on pears. Ten to thirtypercent of the yearly production account for ornamental uses, with use on olive and pineapple crops each accounting for less than 10 percent of the pounds of this production. On apples and pears, NAA is applied to chemically thin the fruit or to prevent preharvest drop. Ornamental uses are mainly for root growth stimulation and for delaying leaf drop. The present formulations of these chemicals are listed in table 2.

TABLE 2

REGISTERED FORMULATIONS OF NAA, ITS SALTS, ESTER & ACETAMIDE

CHEMICAL	FORMULATION TYPE							
	D (%ai)	EC (lb/gal ai)	SC/L (lb/gal ai)	SC/S (%ai)	WP (%ai)	RTU (%ai)	CR (%ai)	PrL (%ai)
NAA	0.2	0.016	0.04-0.28		3.5			
Sodium Salt				3.5-98	2.0 & 7.11		98	
Potassium Salt								
Ammonium Salt			0.44 & 1.76					
Ethyl Ester						1.0		1.0
Acetamide	0.4		0.176		8.4			

D=dust; EC= emulsifiable concentrate; SC/L= soluble concentrate/liquid; SC/S= soluble concentrate/solid; WP= wettable powder; RTU= ready-to-use; CR= crystalline; PrL= pressurized liquid; IM= impregnated material

NAA formulations (D, WP, EC, SC/L, SC/S, and Cr) are applied as foliar sprays to fruit crops, either aerially or using ground equipment that directs the spray up into the trees. Applications for ornamental uses include soil drench (SC/L), manual spraying (WP and SC/L), and dipping plant cuttings (D and SC/L).

2. Foliar Applications

No data are available to assess the environmental fate of NAA and subsequent potential for exposure to humans and wildlife. Similarly, no data are available to quantify the exposure that applicators and their helpers may experience in the handling and application of NAA.

All formulations, except the RTU and PrL formulations, are registered for use as foliar sprays. While spray drift from high-pressure spray equipment and aerial applications may expose humans, livestock, and wildlife outside of the application site, the major exposure will be to workers mixing, loading, and applying NAA. Respiratory and dermal exposure may result from "puff back" of the dry formulations during mixing; ocular exposure could occur during mixing of the liquid formulation. The use of protective clothing should eliminate any hazard associated with this route of exposure.

These chemicals are usually applied by a single person using air blast equipmentcontrolled from a tractor for 8 to 10 hours per day. Mixing/loading of the chemicals and refueling of the tractor occurs approximately 12 to 15 times per day, averaging 10 minutes per stop. A second individual, driving a supply truck, may be involved in application. This second individual may be exposed to the spray drift or solution for not more than 5 to 10 minutes for each hour of spraying.

The air blast equipment used to with these chemicals will apply 200 to 300 gallons per acre, with spray particles reaching a height of up to 25 feet, depending on the orientation of the upper bank of nozzles, air direction vanes on the top of the sprayer, wind conditions, etc.

Regular work clothes are usually worn by the tractor driver and the refilling helper. Coveralls may be worn by some workers and rubber gloves may be worn by individuals handling the concentrated product. Approximately 25% of the tractor operators work in enclosed cabs.

3. Soil Drench and Dip Applications

Ornamental uses of NAA include a soil drench to stimulate rooting and a dip for plant cuttings. Dermal exposure would result to workers during these procedures. However, such exposure will be extremely small considering the small amount of active ingredient found in use dilutions of these chemicals. The half-life of NAA in potting soil and on cut plant surfaces is not known.

D. Summary of Data Gaps

Because of the low application rate and the minor use status of these chemicals the Agency has determined that further environmental fate testing is not required.

CHAPTER VI: TOXICOLOGY

A. Toxicology Profile
B. Human and Domestic Animal Hazard Assessment
C. Summary of Data Gaps

A. Toxicology Profile

1. TECHNICAL CHEMICALS

a. Napthaleneacetic Acid (NAA)

1) Acute Effects

No data were available to assess the acute oral, acute dermal and acute inhalation toxicities of technical NAA, nor are data available to assess the primary eye irritation, primary dermal irritation, and dermal sensitization potential of technical NAA. The above acute toxicity tests must be performed on technical NAA and are so identified in Chapter III of this Standard.

2) Subchronic Effects

In a range-finding study (Huntingdon Research Center, MRID GS-0023-001) male and female Sprague-Dawley rats were given 250, 1000 or 4000 mg/kg/day technical NAA by gavage for 10 consecutive days. All the animals at the highest dose ar one female in the 1000 mg/kg/day dose group died after two to three days. Clinical signs of toxicity which preceded death, included dyspnea, ataxia, lethargy and prostration. Dose related depressions in body weight gain and food consumption were observed. The incidence of gross pathological alterations, which included discolored lungs, liver or kidneys, distended bladder and G.I. tract, was greater in the treated groups. From the doses tested, 250 mg/kg/day appeared to be the maximum tolerated dose.

In another range finding study (Verschuuren et al., MRID 005008106) male and female Wistar rats were fed diets containing 0, 50, 250, 1,250 or 7,500 ppm technical 1-NAA for two weeks. Evidence of toxicity included liver glycogen depletion at the two highest doses, accompanied by a slight increase in relative liver weight at 7500 ppm and a nonsignificant increase in serum SGPT activity at this dose. In addition, an increase in the relative kidney weight at 1250 and 7500 ppm was significant in males. Histological examination demonstrated some changes in the tubular epithelial cells of the kidneys in rats at the 2 highest doses. These changes in the renal tubules were indicative of proteinosis which is caused by the leakage of proteins from the glomeruli and subsequent resorption in the proximal tubes.

Verschuuren et al. (MRID 005008106) also investigated the effect of feeding technical 1-NAA (% A.I. unspecified) in the diet at 0, 200, 1000 or 5000 ppm to male and female rats for 90 days. This study provided supplemental information about the subchronic toxicity of 1-NAA in rats. A reduction in growth and food consumption was observed in males at the highest dose and was accompanied by an increase in the relative liver weight and an induction of liver microsomal enzymes in these same animals. These results demonstrated a dose related reduction in liver glycogen depletion (which was more severe in females) and a centrolobular decrease in liver glucose-6-phosphatase at all levels. Because of these findings, a NOEL could not be determined from this study. The authors indicated that the renal tubular changes observed in the two week range finding study were not observed at 200, 1000 or 5000 ppm in the 90 day study.

The subchronic oral toxicity of technical NAA in rats could be adequately assessed in a 90-day feeding study (CDC RESEARCH, MRID GS-0023-002) in which male and female Sprague-Dawley rats were given 0, 50, 150 or 500 mg/kg/day of technical NAA in the diet. In this study, body weight gain depression (approximately 12 to 13%) was observed in males and females at 500 mg/kg/day. In addition, a significant increase in both relative and absolute liver weight was observed in females at the highest dose. The data indicated a NOEL of 150 mg/kg/day. The authors reported that there was no evidence microscopically of hepatic centrolobular glycogen depletion as reported previously (Veschuuren et al., MRID 005008106). This study fulfills the subchronic oral toxicity data requirement in rats.

In a six-month subchronic oral toxicity study (Elars Bioresearch Laboratories, MRID GS-0023-031) technical NAA (in gelatin capsules) was given to male and female beagle dogs at doses of 0, 50, 150 and 300 mg/kg/day. Glycogen depletion and degenerative changes in the liver were observed at 150 and 300 mg/kg/day. Also, two of eight dogs at 50 mg/kg/day showed slight evidence of pericholangitis that was similar in nature to lesions in the livers of dogs given 150 and 300 mg/kg/day. This study indicates that the dog is more sensitive to the toxic effects of NAA than the rat. A NOEL of 50 mg/kg/day is established from this study based on the following considerations:

- pericholangitis at the lowest dose level was slight and reflects a very low to no effect on liver function,

- the lesion is reversible and reflects a slight inflamation process resticted to the portal areas of the liver

- while dose related, the lesion is considered to be mild.

No further subchronic oral testing in the dog is required.

An adequate study was available to assess the teratogenic potential of technical NAA in rats. (Huntington Research Center, MRID GS-0023-044). In this study technical NAA at concentrations of 0, 10, 50 or 250 mg/kg (in supension with 0.05% sodium carboxymethylcellulose) was given (by gavage) to pregnant CD rats on gestation days 6 through 15. No teratological effects were observed. A decrease in maternal body weight was observed at 250 mg/kg, however this was not accompanied by fetotoxicity. The data indicated that the NOEL for teratology for NAA technical in rats is greater than 250 mg/kg. The NOEL for maternal toxicity was 50 mg/kg. This study fulfills the teratology data requirement for NAA in one mammalian species. Testing in a second species is required.

3) Chronic Effects

In a 19 month oncogenicity study (Bionetics Research Labs, MRID 005010016) NAA, at 100 mg/kg by a single subcutaneous injection (in DMSO) or at 215 mg/kg by oral intubation (in 0.5% gelatin) for 21 days and in the diet at 517 ppm for the remainder of 18 months, was evaluated for carcinogenicity in two hybrid strains of mice, B6C3F1 and B6AKF1. No significant difference was observed between the tumor incidence of mice treated with NAA and mice in the negative control groups. However, the number of animals tested in each group was too small to adequately evaluate the carcinogenic potential of NAA in mice. In addition, the sensitivity of this assay is diminished since, one of the chemicals used as a positive control, isosafrole, gave equivocal evidence of oncogenicity. While this study does not meet the Agency's current requirements for oncogenicity testing, it does provide an initial screen of the oncogenic potential of NAA. Since positive results were not demonstrated and since these chemicals are minor use chemicals, the Agency has determined that further oncogenicity testing will not be required at this time.

4) Mutagenic Effects

Adequate data were available to assess the mutagenic potential of technical 1-NAA in bacterial assays. In a study, (Pharmakon Laboratories, MRID GS-0023-041) 1-NAA at concentrations of 0.5, 2, 8, 40, 200, 1000 or 5000 ug/plate was non-mutagenic in Salmonella typhimurium strains TA 1535, TA 1537, TA 1538, TA 98 and TA 100 when tested with and without metabolic activation. This assay detects reverse mutations resulting from base pair substitution or frameshift events. The data can be considered sufficient to fulfill the mutagenicity da requirement for microbial point mutation testing.

In another study, (Pharmakon Labortories, MRID GS-0023-040) technical 1-NAA (in water or 10% DMSO) at concentrations of 10, 20 and 40 ug/plate did not produce a zone of inhibition when added to cultures of Escherichia coli DNA repair deficient strain P 3478 or DNA repair competent strain W3110, with and without metabolic activation. Positive controls, ethylmethanesulfonate and diethylnitrosamine did cause zones of inhibition under similar testing conditions. The lack of a zone of inhibition with 1-NAA in this assay should be interpreted as demonstrating that NAA does not interact with DNA in Escherichia coli.

Studies were available to assess the effects of technical 1-NAA in yeast. (Pharmacon Laboratories, MRID GS-0023-037; Pharmacon Laboratories, MRID GS-0023-038; Pharmacon Laboratories, MRID GS-0023-039). In these assays, technical 1-NAA was evaluated for its effects on mitotic crossing over, reverse mutation and gene conversion in Saccharomyces cerevisiae strain D-7.

In the mitotic crossover assay, 1-NAA at concentrations of 10^{-6} to 10^{-2} M did not have mutagenic activity in heteroallelic ade 2-40/ade 2-119 diploid strain D-7 Saccharomyces cervisiae, when tested without metabolic activation.

In a reverse mutation assay, 1-NAA at concentrations of 10^{-6} to 10^{-2} M did not have mutagenic activity in homoallelic ilv - I - 92/ilv - I- 92 diploid strain D-7 Saccharomyces cervisiae, when tested without metabolic activation.

In the mitotic gene conversion assay 1-NAA at concentrations of 10^{-6} to 2.1 $\times 10^{-2}$ M did not have mutagenic activity in heterallelic diploid trp 5-12/trp 5-27 strain D-7 *Saccharomyces cervisiae*, when tested without metabolic activation.

The above assays indicated that 1-NAA was nontoxic to the yeast at concentrations as high as 10^{-2} M. This finding and the lack of genetic activity in all three assays indicate that 1-NAA is inactive in *Saccharomyces cervisiae* strain D-7 yeast.

In another study (Doi et al., MRID 005008826), NAA was evaluated for its ability to induce large cell mutants in *Saccharomyces cerevisiae* haploid strain H 40. This study suggests that NAA, at 500 ug, induced changes in the ploidy of these cells. These data cannot be interpreted as indicating that NAA has genetic activity in this strain of yeast because a change in ploidy does not necessarily reflect an effect on DNA.

Supplementary data were available to evaluate the *in vivo* cytogenetic effects of technical 1-NAA (Pharmakon Laboratories, MRID GS-0023-042). In a study, male and female mice were pretreated for two days with 60 or 125 mg/kg of NAA (in water) by intraperitoneal injection. Six hours after the second dose the animals were killed, their femurs were removed and the bone marrow aspirated. Polychromatic erythrocytes were counted for the presence of micronuclei (an indication of chromosomal breaking effects of the chemical). The results for NAA were negative while TEM (triethylenemelamine), the positive control, gave a statistically significant increase (over vehicle control) in the number of micronuclei per 1000 polychromatic erythrocytes. Since no cell counts were made, the sensitivity of this assay is diminished. It is possible that NAA was toxic to the cells; in this event, an increased number of micronuclei may not have been detected.

A dominant lethal study with technical 1-NAA is available (Pharmakon Laboratories, MRID GS-0023-043). In this study male rats were given 1-NAA in 0.25% methylcellulose by oral intubation at concentrations of 125, 250 or 500 mg/kg for five consecutive days. Subsequently the males were mated with virgin females. Matings were repeated for a total of eight weeks. Vehicle and positive control (triethylenemelamine (TEM) groups were run under similar testing conditions. The results indicated that NAA did not produce dominant lethal effects in male rats as measured by preimplantation and post-implantation losses. Post-implantation fetal deaths were significantly increased after the first four matings in dams mated to males given TEM, the positive control. This study is adequate to assess the dominant lethal effect of NAA. It can be concluded that NAA, at concentrations as high as 500 mg/kg, does not produce dominant lethal effects in rats.

The above identified studies are adequate to evaluate NAA for its mutagenic potential. Although some of the studies, by themselves, were insufficient to assess the mutagenic potential of NAA, as a whole the data indicate that NAA has a low potential for inducing genetic effects. Further mutagencity testing with NAA, its salts, ester and acetamide is not required.

5) Metabolic Effects

An adequate metabolism study is available with carboxyl-labeled naphthaleneacetic acid C^{14}(1-NAA-C^{14}) in rats. (Letcho and Brouwer, MRID 000004942). In this study, male rats were given single oral doses of 0.1, 1.0, 100 or 250 mg of 1-NAA-C^{14} (in sodium hydroxide). Radioactivity in the urine and feces was monitored daily for three days. The results indicated that 71 to 90% of the radiolabel was excreted in the urine and 3 to 21% was excreted in the feces within three days. The two major urinary metabolites (70 to 93%) were naphthaceturic and naphthacetyglucosiduronic acids. It was observed that at the lower doses, approximately 90% of the radioactivity was excreted in the urine in the first 24 hours.

In this study, rats with cannulated bile ducts were given single oral doses of 0.1 or 100 mg of 1-NAA-C^{14}. The radioactivity of the urine and bile was monitored every two hours (up to six hours). The results showed that 4 to 21% of the radiolabel collected during this time was biliary, while 1 to 53% of it was urinary. At the high dose, the major metabolite was the glucuronic acid conjugate (i.e. naphthylglucosiduronic acid) while at the low dose the major metabolite was the glycine conjugate (i.e. napthylaceturic acid). In summary, this study indicated that 1-NAA and its metabolites are rapidly excreted in the urine and feces of rats. In addition, it was shown that rats have a greater capacity for glucuronic acid conjugation.

Additional information concerning the metabolism of 1 NAA-C^{14} in man, primates, rodents, cat and bat was available (Dixon et al., MRID 005008052). this study 100 mg/kg of 1-NAA-C^{14} (in sodium hydroxide) was given intramuscularly to 6 primate species, intraperitoneally to the cat, rat and bat, and orally to the rabbit. In addition, 5 mg of 1-NAA-C^{14} (orally) was given to a man. In most species tested 60 to 100% of the radioactivity was excreted in the urine by 48 hours. The glucuronic acid conjugate was the major urinary metabolite in man, rhesus monkey, marmoset, rabbit, rat and fruit bat. In the cat, no glucuronic acid conjugate was excreted; taurine and glycine conjugates were the major excretion products.

Also, in this study female rats with cannulated bile ducts were given 5 to 500 mg/kg 1-NAA-C^{14} intraperitoneally. After three hours, 10 to 44% of the radioactivity was present in the bile and 0.6 to 32% was present in the urine. At the highest doses, glucuronic acid conjugation predominated whereas at the lower doses there appeared to be a similar amount of glycine and glucuronic acid conjugation.

The above data are adequate to characterize the metabolism of 1-NAA. It is expected that the ethylester of 1-NAA and naphthaleneacetamide will be metabolized similarly once they are degraded to their respective alcohol and salt, and NAA by gastro-intestinal esterases and amidases. No additional metabolism studies are required with these chemicals.

b. Salts

1) Acute Effects

No data were available to assess the acute oral, acute dermal and acute inhalation toxicities of the technical sodium, potassium or ammonium salts of NAA. Since it is expected that the acute toxicities of the sodium and potassium salts of NAA will be comparable to those of the acid, testing with these chemicals is not required. The acute toxicity of the ammonium salt will be assessed once the data are available for the acid.

No data were available to assess the primary eye irritation, primary dermal irritation and dermal sensitization potentials of the technical sodium, potassium or ammonium salts. It is expected that sodium and potassium salts of NAA will have similar eye and dermal irritation potentials and dermal sensitization potentials as the acid; therefore, testing of these chemicals is not required.

The ammonium salt is not expected to cause dermal irritation or dermal sensitization greater than that resulting from exposure to the acid; therefore, these tests are not required. However, the ammonium salt may have eye irritant properties that are greater than those caused by exposure to the acid; therefore, an eye irritation study with this salt is required.

2) Subchronic/Chronic/Mutgenicity Effects

Subchronic, chronic and mutagenicity toxicity testing with the technical sodium, potassium or ammonium salts is not required, since the subchronic, chronic and mutagenic toxicity of these chemicals is expected to result from exposure to the acid.

c. Ester

1) Acute Effects

An adequate acute oral toxicity study in rats (Affiliated Medical Research, MRID GS-0023-048) was available with technical NAA- ethyl ester. In this study, NAA-ethyl ester in water, was given to three groups of male rats by oral intubation. The LD_{50} was determined to be 3580 + 333.3 mg/kg. Gross autopsy findings from the animals that died during the study included hemorrhagic stomach, intestines and lungs, fluid and gas filled intestines and stomach, discolored spleen and kidneys, mottled liver, dialated mesenteric blood vessels, wet genital area and bloody nose. These data are sufficient to fulfill the acute oral toxicity data requirement for the technical ethyl ester of NAA and place this product in Toxicity Category III.

An adequate acute dermal toxicity study in rabbits with technical NAA ethyl ester was available. (Affiliated Medical Research, MRID GS-0023-047). In this study the acute dermal LD_{50} in male albino rabbits was determined to be greater than 5 g/kg. No mortality was observed when four male albino rabbits were given 24 hour dermal exposure to 5 g/kg of technical NAA-ethyl ester. The test material was applied to the shaved, unabraded skin under an occlusive rubber wrap. No signs of toxicity or gross pathological alterations were observed. These data are sufficient to fulfill the acute dermal toxicity data requirement for the technical ethyl ester of NAA and place this product in Toxicity Category III.

Sufficient data were available to assess the acute inhalation toxicity of technical NAA ethyl ester in rats. (Affiliated Medical Research, MRID GS-0023-046). In this test, the LC_{50} was determined to be greater than 206.5 mg/L. No mortalities were observed when six male albino rats were given one hour inhalation exposure to a nominal concentration of 206.5 mg/L of aerosol technical ethyl ester of NAA in a 50% suspension with water. Following exposure, signs of toxicity were irritation and lethargy. The animals appeared normal by the second day. No gross pathological alterations were observed. These data are adequate to fulfill the acute inhalation toxicity data requirement and place technical ethyl ester of NAA in toxicity category IV.

The above data indicate a low acute toxicity potential for the ethyl ester in humans.

Adequate data were available to evaluate the primary eye irritation potential of technical NAA-ethyl ester. (Affiliated Medical Research, MRID GS-0023-045). In this study, 0.1 ml of the test chemical was instilled into the left conjunctival sac of the eyes of nine male albino rabbits. Six eyes were washed two or four seconds after instillation. No irritation was observed to the cornea, iris or conjunctiva in washed and unwashed eyes. The primary eye irritation score was 0 (out of a possible 110). These data are sufficient to fulfill the primary eye irritation data requirement for the technical ethyl ester of NAA. The chemical should not be considered a primary eye irritant and it should be placed in Toxicity Category IV.

Since the ethyl ester did not produce eye irritation in rabbits and since no gross pathological skin alterations were observed in rabbits in an acute dermal toxicity study with this chemical, it is expected that the ethyl ester will have a low potential for dermal irritation in humans. No further dermal irritation testing is required.

No data were available to assess the dermal sensitization potential of the ester. It is expected that the dermal sensitization potential of this ester will be similar to that of the acid; therefore, additional testing is not required.

2) Subchronic/Chronic/Mutagenic Effects

In an inadequate study by Finch and Hartzell (MRID 005022160), female mice were fed diets containing 0, 0.95, 9.5, 29 or 86 ppm of alpha naphthalene acetic acid methyl ester for 1-1/2 to 2 years. No significant differences in body weight gain or survival and no pathological alterations attributed to the test material were reported. The study was insufficient to assess the chronic toxicity of NAA; the number of animals treated at each dose level was low (20 mice/dose) and only females were tested. Animals were housed in group cages and weighed by group; individual body weights were not determined. There was no food consumption data, clinical testing was not performed, and histopathological examinations were not made.

Finch and Hartzell (MRID 005022160) also investigated the reproductive effects of alpha naphthalene acetic acid methyl ester in the diet at concentrations of 0, 0.95, 9.5 29 or 86 ppm in mice. No reproductive toxicity, through the third generation was observed however, the study is insufficient to evaluate the reproductive toxicity of NAA. The number of animals bred was low and females were bred to yield only one litter. Inadequate information was available for fertility, lactation and viability. No body weight data were available for the pregnant dams, and no data were available for gestation. There were no observation data for the pups; there were no data to indicate the number of pups found dead at birth. The data for pup body weight was inadequate and there were no pathology data for the pups. In addition, the authors indicated that no toxicity was observed even at the highest doses.

While the above studies were performed with the methyl ester and do not meet with current scientific standards, the Agency has determined that additional reproductive and chronic feeding testing with technical NAA will not be required at this time, since these chamicals are minor use chemicals and available data do not indicate major concerns in these areas.

Subchronic, chronic and mutagenicity toxicity testing with the technical ethyl ester of NAA is not required, since the subchronic, chronic and mutagenic toxicity of this chemical is expected to result from exposure to the acid, through in vivo metabolism.

d. Acetamide

1) Acute Effects

Because these are minor use chemicals no acute testing with technical naphthaleneacetamide is required at this time.

2) Subchronic/Chronic/Mutagenic Effects

Subchronic, chronic and mutagenicity toxicity testing with the technical naphthaleneacetamide is not required, since the subchronic, chronic and mutagenic toxicity of this chemical is expected to result from exposure to the acid, through in vivo metabolism.

2. FORMULATED PRODUCTS

a. Soluble Concentrates

1) NAA

Because these are minor use chemicals, except for the primary eye irritation study mentioned below, no acute toxicity testing will be required at this time.

Primary eye irritation testing with soluble concentrates containing greater than 50% petrolium oil or diacetone is required.

2) Salts

Sodium Salt

Because these are minor use chemicals, no acute toxicity testing will be required at this time.

Potassium Salt

Because these are minor use chemicals, except for the primary eye irritation study mentioned below, no acute toxicity testing will be required at this time.

Primary eye irritation testing with soluble concentrates containing the greater than 25% isopropanol is required.

Ammonium Salt

Because these are minor use chemicals no acute toxicity testing will be required at this time.

3) Ester

An adequate acute oral toxicity study in rats with a soluble concentrate containing 15.1% NAA-ethyl ester was available. (Affiliated Medical Research MRID GS-0023-035). In this study, the test material (in water) was given to three groups of male rats by oral intubation. The LD_{50} was determined to be 5585 ± 760 mg/kg. Signs of toxicity included hypoactivity in one rat at the highest dose (10g/kg), from one hour after dosing until death. Gross autopsy findings from the animals that died during the study included hemorrhagic stomach, intestines and lungs, fluid and gas filled intestines and stomach, blanched and slightly pitted kidneys, mottled spleen, bloody nose and stained genital area. These data are sufficient to fulfill the acute oral toxicity data requirement for the 15.1% soluble concentrate of NAA-ethyl ester and place the product in Toxicity Category IV.

An adequate acute dermal toxicity study in rabbits was available with a soluble concentrate containing 15.1% NAA-ethyl ester (Affiliated Medical Research, MRID GS-0023-032). In this study, the LD_{50} was determined to be greater than 5 g/kg. No mortality was observed when four male albino rabbits were given 24 hour dermal exposure to 5 g/kg of the product. The test material was applied to the shaved, unabraded skin of the rabbits under an occlusive rubber wrap. No signs of toxicity were observed. Gross pathological examination indicated eschar formation at the site of application. These data are sufficient to fulfill the acute dermal toxicity data requirement for the 15.1% soluble concentrate of NAA-ethyl ester and place this product in toxicity Category III.

Adequate data were available to assess the acute inhalation toxicity of a soluble concentrate containing 15.1% NAA ethyl ester in rats. (Affiliated Medical Research, MRID GS-0023-034). In this study, the LC_{50} was determined to be greater than 217.1 mg/L. No mortalities were observed when 6 male albino rats were given one hour inhalation exposure to a nominal concentration of 217.1 mg/L of the soluble concentrate in a 50% w/v emulsion with water. Following exposure, signs of toxicity were irritation and lethargy. The animals appeared normal by 8-24 hours after exposure. No abnormal gross pathological alterations were observed. These data are sufficient to fulfill the acute inhalation toxicity data requirement for the 15.1% soluble concentrate of NAA ethyl ester and place this product in Toxicity Category IV.

The above data indicate a low acute toxicity potential for the 15.1% ethyl ester in humans.
Adequate data were available to evaluate the primary eye irritation potential of a soluble concentrate containing 15.1% of NAA-ethyl ester. (Affiliated Medical Research, MRID GS-0023-033). In this study the test chemical was determined to be a primary eye irritant. When 0.1 ml of the test material was instilled into the left conjunctival sac of the eyes of nine male albino rabbits (with six of the eyes being washed two to four seconds after instillation) corneal opacity that persisted for at least seven days was observed in eight out of nine eyes. In addition, moderate to severe irritation of the conjunctiva and iris persisted for at least seven days in some animals. At 14 days, damage that was described as irreversible by the pathologist was observed. These data are sufficient to evaluate the primary eye irritation potential of the 15.1% soluble concentrate of NAA-ethyl ester and place the product in Toxicity Category I; indicating that the product is corrosive and may cause irreversible eye damage in humans.

No data were available to evaluate the primary dermal irritation or dermal sensitization potential of products containing 15.1% of the ethyl ester. Testing is not required at this time.

4) Acetamide

Because these are minor use chemicals, except for the primary eye irritation study mentioned below, no acute toxicity testing will be required at this time.

Primary eye irritation testing with soluble concentrates containing greater than 50% isopropanol and greater than 50% fertilizer is required.

b. Wettable Powders/Dusts

Because these are minor use chemicals no acute toxicity testing will be required at this time.

c. Pressurized Liquids

Because these are minor use chemicals no acute toxicity testing will be required at this time.

B. Human and Domestic Animal Hazard Assessment

The present uses of these chemicals indicate that the actual residues on foods would be extremely low. Actual residues and theoretical calculations of residues, presented in the Environmental Fate chapter, confirm that residues will be extremely low.

Despite the fact that the method of application will result in high exposure to the spray, the very low amounts of active ingredient in the spray will result in a low exposure.

Acute exposure of applicators to the concentrated form of these chemicals during mixing/loading constitutes a scenario of concern to the Agency. Data which demonstrate the acute toxicity category associated with the technical chemicals are the Agency's primary concern and these concerns are reflected in the Agency's data requirements.

C. Summary of Major Toxicology Data Gaps

Many of the studies which have been reviewed meet the Agency's current requirements. Some studies (e.g., oncogenicity, reproduction) are inadequate but do not indicate major concerns in these areas. Because the available data do not indicate major toxicological concerns and because these are minor use chemicals with low dietary and applicator exposure, the Agency has determined that no further testing, except for some acute and irritation studies and a teratogenicity study listed in Chapter III, will be required at this time.

CHAPTER VII: RESIDUE CHEMISTRY

A. Residue Chemistry Profile
B. Summary of Data Gaps

A. Residue Chemistry Profile

Naphthaleneacetic acid is marketed in the U.S. as a plant growth regulator to control fruit drop or thinning on apples, pears, quinces, and olives and to control flower induction on pineapples. Tolerances have been established for NAA on apples, pears, and quinces at 1 ppm; on olives at 0.1 ppm; and in or on pineapples at 0.05 ppm (as the sodium salt) (40 CFR 180.155). Tolerances have also been established for the ethyl ester on apples and pears at 1 ppm and 0.1 ppm on olives (40 CFR 180.309). Tolerances have also been established for the acetamide on apples and pears at 0.1 ppm (40 CFR 180.309). No tolerances are pending. No CODEX tolerances exist for these chemicals.

The major residue in olives is NAA, the parent compound. Metabolites in olives are 1-naphthaleneacetylaspartic acid (NAAsp) and B-D-glucose-1-naphthaleneacetate (NAG) (Crosby et al., MRID 000004943). The major residue in apples and pears is B-D-glucose-1-naphthaleneacetate, followed by 1-naphthaleneacetylaspartic acid, and then by NAA (Bukovac et al., MRID 005009196). Although no metabolism data are available on pineapples, data on other fruits indicate that NAG, NAAsp, and NAA would be the residues of concern, although not necessarily in that order. Metabolism data on apples can be applied to quinces since these two fruits are related and quinces are a minor crop use for these chemicals. The metabolism of NAA in plants is adequately defined and no further testing is required. Metabolism data on related compounds (i.e. the salts, ester, and amide of NAA) are not needed if data showing rapid dissociation or hydrolysis to the acid are submitted.

The two major metabolites in rat urine are the conjugates of NAA with glucuronic acid and with glycine (Lethco et al., MRID 000004942; French et al., MRID 005007966; Dixon et al., MRID 005008052; Dixon, MRID 005008057). Metabolites in excrement of the hen are conjugates of NAA with taurine and ornithine (Idle et al., MRID 005008070). The major and minor metabolites in human urine are 1-napthylacetylglucuronide and 1-naphthylacetyltaurine, respectively (Dixon et al., MRID 005008052). No ruminant metabolism study is available. It is concluded that the metabolism of NAA in animals is adequately defined, provided residues do not occur in feed items.

Adequate analytical methods are available for determination of residues and enforcement of tolerances for 1-naphthaleneacetic acid on olives (Crosby et al., MRID 000004943; Zweig et al., MRID 000004916), for the ethyl ester on olives, and for 1-naphthaleneacetamide on apples (Sigrist, MRID 005007967; Cochrane et al., MRID 005020083), pears and olives. Adequate analytical methods are available for the determination of NAA itself on apples (Randall, MRID 005002768; Cochrane et al., MRID 005008121; Bache et al., MRID 005008068), pears, and pineapple (Young et al., MRID 000004946), and for the ethyl ester itself (plus NAA) on pears (Amchem Products, MRID GS-0023-012; Amchem Products, MRID GS-0023-019; Amchem Products, MRID GS-0023-036) and apples. No analytical methods are available for quinces. Available residue data indicate that residues in olives would be less than 0.1 ppm after treatment with Fruit Fix Super Concentration 800. No detectable residues are expected to occur in apples, pears, and olives after treatment with Tre-Hold Sprout Inhibitor A112. Lack of residue data on representativeformulations and uses constitutes a data gap. The limited data which are available indicate that no residues will result in meat, milk, poultry, or eggs from the registered uses. There are no records in EPA or FDA of incidents involving the enforcement of the tolerances.

B. Summary of Data Gaps

1. Dissociation or hydrolysis data on all chemicals.
2. Data indicating whether residues in plants of esters, salts and acetamides of NAA degrade rapidly to NAA.
3. Additional residue data reflecting the registered uses for apples and pears representative of the chemical forms of NAA and registered formulations.
4. Residue data on pineapples and olives are requested which reflect currently registered uses and formulations.

If the data required in 1 and 2 indicate that the various chemical forms of NAA are similar from a residue standpoint, then the additional residue data required in 3 and 4 in this summary can be kept to a minimum with specific study requests.

CHAPTER VIII: ECOLOGICAL EFFECTS

A. Plant Effects Profile
B. Animal Effects Profile
C. Summary of Data Gaps

A. Plant Effects Profile

The effects of NAA to nontarget aquatic plants is not known. NAA at 620 ppb caused a 50 percent reduction in root growth of soaked pea roots. There was only a 10 percent reduction in root growth when NAA was applied to the hypocotyl or young stem of peas at 500 ppm. (Elliasson, MRID 005007254) NAA reduces growth in cucumber seedlings with a NOEL of 98 ppb (Hilton & Nomura, MRID 005007255). The germination of lettuce, tomato, sugarbeet or dwarf bean was unaffected in their yields when the seeds were treated with 100,000 ppm NAA applied in talc (Croxall & Ogilvie, MRID 005012526). Concentrations of 0.1 ppm in a seed soak, however, delayed or inhibited germination of cotton. NAA at 100 ppm inhibited germination of cotton for 10-14 days without affecting yields (Coats, MRID 005010399).

The concentration of NAA in the spray solution ranges from 10 to 50 ppm for registered fruit crops and also for decidious trees. The extent of exposure to nontarget terrestrial plants is minimal given the low concentration and, therefore, the hazard is judged to be minimal.

B. Animal Effects Profile

Naphthalene acetic acid (NAA acid) possesses a very low toxicity to Bobwhite Quail when taken as a single oral dose. The acute oral LD_{50} for Bobwhite Quail is greater than 2510 mg/kg (Truslow Farms, MRID GS-0023-024). The acute oral LD_{50} for Mallard Ducks cannot be determined because the use of immature test animals has compromised the validity of this study (Truslow Farms, MRID GS-0023-023).

Naphthalene acetic acid (NAA acid) possesses a very low toxicity to Bobwhite Quail and Mallard Ducks, when taken ingested along with their regular diet. The subacute oral LC_{50} for Bobwhite Quail and Mallard Ducks are both greater than 10,000ppm (Truslow Farms, MRID GS-0023-025; Truslow Farms, MRID GS-0023-026).

While the LC_{50} values for the two freshwater fish and the aquatic invertebrate show that a formulated product, Amchem Tre-Hold Sprout Inhibitor A112, is slightly toxic to aquatic life (Union Carbide Environmental Services, MRID GS-0023-022; Union Carbide Environmental Services, MRID GS-0023-050; Union Carbide Environmental Services, MRID GS-0023-051).

C. Summary of Major Data Gaps

The Agency cannot presently estimate the hazards to aquatic life posed by the technical chemicals because the proper toxicity tests have not been performed on technical NAA. Before a hazard evaluation can be completed, the Agency must have proper data on the acute toxicity of technical NAA to warmwater and coldwater fish, an aquatic invertebrate, aquatic and terrestrial macrophytes, and algae.

CASE BIBLIOGRAPHY

Guide to Use of This Bibliography

1. Content of Bibliography. This bibliography contains citations of all the studies reviewed by EPA in arriving at the positions and conclusions stated elsewhere in this standard. The bibliography is divided into two sections: (1) citations in numerical order that contributed information useful to the review of the chemical and are considered to be part of the data base supporting registrations under the standard, and (2) an alphabetical listing of all documents reviewed by the Agency. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions, and the published technical literature.

2. Units of Entry. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to a published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. Identification of Entries. The entries in this bibliography are sorted by author, date of the document, and title. Each entry bears, to the left of the citation proper, a nine-digit numeric identifier. This number is unique to the citations and should be used at any time specific reference is required. This number is called the "Master Record Identifier" or "MRID". It is not related to the six-digit "Accession Number", which has been used to identify volumes of submitted data; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. This is also to be used whenever a specific reference is needed.

4. Form of the Entry. In addition to the Master Record Identifier (MRID), each entry consists of a bibliographic citation containing standard elements followed, in the case of materials submitted to EPA, by a description of the earliest known submission. The bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs. Some explanatory notes of specific elements follow:

   a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first known submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. This is the third element in the citation. In some cases it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to us in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submissions:

(1) Submission Date. Immediately following the word 'received' appears the date of the earliest known submission, at the time that particular document was processed into the Pesticide Document Management System.

(2) Administrative Number. The next element, immediately following the word 'under', is the registration number, experimental permit number, petition number, or other administrative number associated with the earliest known submission, at the time that particular document was processed into the Pesticide Document Management System.

(3) Submitter. The third element is the submitter, following the phrase 'submitted by'. When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification. The final element in the trailing parenthesis identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol 'CDL', standing for "Company Data Library". This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th,123456-AA.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD NUMERICAL BIBLIOGRAPHY
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OFFICE OF PESTICIDE PROGRAMS
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